UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2023

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 001-38890

Quince Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**90-1024039**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
601 Gateway Boulevard, Suite 1250. South San Francisco, California	**94080**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (415) 910-5717

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	QNCX	The Nasdaq Stock Market LLC
Series A Junior Participating Preferred Purchase Rights	N/A	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 6, 2023, the registrant had 42,868,947 shares of common stock, $0.001 par value per share, outstanding.

Table of Contents

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

Quince Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)
(In thousands, except share and per share amounts)

	September 30, 2023	December 31, 2022 [1]
ASSETS		
Current assets:		
Cash and cash equivalents	$ 21,632	$ 44,579
Short term investments	61,593	45,602
Prepaid expenses and other current assets	1,448	3,567
Note receivable	500	—
Total current assets	85,173	93,748
Assets held for sale	82	—
Property and equipment, net	5	393
Operating lease right-of-use assets, net	48	291
Long term investments	—	3,578
Intangible asset	—	5,900
Equity investments in Lighthouse Pharmaceuticals, Inc.	78	—
Total assets	$ 85,386	$ 103,910
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 409	$ 570
Accrued expenses and other current liabilities	1,844	2,499
Total current liabilities	2,253	3,069
Deferred tax liabilities	—	248
Total liabilities	2,253	3,317
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 authorized, no shares issued and outstanding as of September 30, 2023 and December 31, 2022	—	—
Common stock, $0.001 par value, 100,000,000 shares authorized, 36,343,632 and 36,136,480 issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	36	36
Additional paid in capital	393,331	389,105
Accumulated other comprehensive income (loss)	516	(289)
Accumulated deficit	(310,750)	(288,259)
Total stockholders' equity	83,133	100,593
Total liabilities and stockholders' equity	$ 85,386	$ 103,910

(1) The balance sheet as of December 31, 2022 is derived from the audited financial statements as of that date

See accompanying notes.

Quince Therapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 1,431	$ 2,451	$ 6,013	$ 22,410
General and administrative	4,663	4,344	12,786	22,461
Goodwill impairment charge	—	825	—	825
Intangible asset impairment charge	—	—	5,900	—
Total operating expenses	6,094	7,620	24,699	45,696
Loss from operations	(6,094)	(7,620)	(24,699)	(45,696)
Interest income	959	315	2,464	532
Other expense, net	(216)	(616)	(504)	(1,246)
Net loss before income tax benefit	(5,351)	(7,921)	(22,739)	(46,410)
Income tax benefit	—	—	248	284
Net loss	(5,351)	(7,921)	(22,491)	(46,126)
Other comprehensive income (loss):				
Foreign currency translation adjustments	158	343	309	481
Unrealized gain (loss) on available for sales securities	101	(130)	496	(655)
Total comprehensive loss	$ (5,092)	$ (7,708)	$ (21,686)	$ (46,300)
Net loss per share - basic and diluted	$ (0.15)	$ (0.22)	$ (0.63)	$ (1.41)
Weighted average shares of common stock outstanding - basic and diluted	36,073,040	35,612,749	35,941,234	32,758,132

See accompanying notes.

Quince Therapeutics, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)
(In thousands, except share and per share amounts)

For the three months ended September 30, 2023 and 2022						
	Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Income / (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance June 30, 2023	36,327,995	$ 36	$ 391,990	$ 257	$ (305,399)	$ 86,884
Issuance of common stock on exercise of stock options and vesting of restricted stock units	70,394	—	28	—	—	28
Restricted stock award retirement	(54,757)	—	(18)	—	—	(18)
Stock based compensation	—	—	1,331	—	—	1,331
Foreign currency translation adjustment	—	—	—	158	—	158
Unrealized gain on available for sale investments	—	—	—	101	—	101
Net loss	—	—	—	—	(5,351)	(5,351)
Balance September 30, 2023	36,343,632	$ 36	$ 393,331	$ 516	$ (310,750)	$ 83,133
Balance June 30, 2022	35,977,688	$ 36	$ 386,766	$ (466)	$ (274,804)	$ 111,532
Issuance of common stock on exercise of stock options and vesting of restricted stock units	152,618	—	13	—	—	13
Stock based compensation	—	—	694	—	—	694
Foreign currency translation adjustment	—	—	—	343	—	343
Unrealized loss on available for sale investments	—	—	—	(130)	—	(130)
Net loss	—	—	—	—	(7,921)	(7,921)
Balance September 30, 2022	36,130,306	$ 36	$ 387,473	$ (253)	$ (282,725)	$ 104,531

See accompanying notes.

Quince Therapeutics, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)
(In thousands, except share and per share amounts)

For the nine months ended September 30, 2023 and 2022						
	Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Income / (Loss)	Accumulated Deficit	Shareholders' Equity
	Shares	Amount				
Balance January 1, 2023	36,136,480	$ 36	$ 389,105	$ (289)	$ (288,259)	$ 100,593
Issuance of common stock on exercise of stock options and vesting of restricted stock units	270,445	—	110	—	—	110
Restricted stock award retirement	(63,293)	—	(18)	—	—	(18)
Stock based compensation	—	—	4,134	—	—	4,134
Foreign currency translation adjustment	—	—	—	309	—	309
Unrealized gain on available for sale investments	—	—	—	496	—	496
Net loss	—	—	—	—	(22,491)	(22,491)
Balance September 30, 2023	36,343,632	$ 36	$ 393,331	$ 516	$ (310,750)	$ 83,133
Balance January 1, 2022	30,074,412	$ 30	$ 355,234	$ (79)	$ (236,599)	$ 118,586
Issuance of common stock in connection with open market sales agreement, net of issuance costs of $19	51,769	—	608	—	—	608
Issuance of common stock on exercise of stock options and vesting of restricted stock units	484,125	—	148	—	—	148
Stock based compensation	—	—	14,986	—	—	14,986
Share issuance in connection with acquisition of Novosteo, Inc.	5,520,000	6	16,497	—	—	16,503
Foreign currency translation adjustment	—	—	—	481	—	481
Unrealized loss on available for sale investments	—	—	—	(655)	—	(655)
Net loss	—	—	—	—	(46,126)	(46,126)
Balance September 30, 2022	36,130,306	$ 36	$ 387,473	$ (253)	$ (282,725)	$ 104,531

See accompanying notes.

Quince Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	For the Nine Months Ended September 30,	
	2023	**2022**
Cash flows from operating activities		
Net Loss	$ (22,491)	$ (46,126)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation	4,134	14,986
Depreciation and amortization	18	162
Impairment loss on operating lease	66	136
Loss on disposal of fixed assets	71	77
Equity investment in Lighthouse Pharmaceuticals, Inc.	(78)	—
Non-cash goodwill impairment charge	—	825
Non-cash intangible impairment charge	5,900	—
Amortization of (discount) premium on available for sale investments	(1,313)	83
Change in deferred tax liabilities due to acquisition of Novosteo, Inc.	(248)	(284)
Changes in operating assets and liabilities, net of acquisitions:		
Prepaid expenses and other current assets	2,272	2,396
Right-of-use assets and lease liabilities	192	—
Other assets	—	175
Accounts payable	(161)	(5,329)
Accrued expenses and other current liabilities	(576)	(5,304)
Net cash used in operating activities	(12,214)	(38,203)
Cash flow from investing activities:		
Purchase of investments	(95,116)	(66,767)
Proceeds from maturities of investments	84,514	55,495
Cash acquired from Novosteo, Inc.	—	10,593
Note receivable	(500)	—
Proceeds from disposal of fixed assets	90	70
Purchase of property and equipment	(136)	(55)
Net cash used in investing activities	(11,148)	(664)
Cash flows from financing activities:		
Payments of finance leases	(6)	(31)
Proceeds from issuance of common stock upon exercise of stock options	92	148
Proceeds from issuance of common stock in connection with open market sales agreement, net of issuance costs	—	608
Net cash provided by financing activities	86	725
Effect of exchange rate changes on cash	329	227
Net decrease in cash and cash equivalents	(22,947)	(37,915)
Cash and cash equivalents at beginning of period	44,579	69,724
Cash and cash equivalents at end of period	$ 21,632	$ 31,809
Supplemental disclosures of non-cash information:		
Net assets acquired of Novosteo, Inc. in exchange for common stock	$ —	$ 16,503
Right-of-use assets obtained in exchange for new operating lease liabilities	$ —	$ 256
Right-of-use asset and financing lease liability reduction as a result of lease modification	$ (70)	$ —
Right-of-use asset and operating lease liability reduction as a result of lease modification	$ —	$ (640)

See accompanying notes.

Note 1. Organization

Description of Business

Effective August 1, 2022, Cortexyme Inc. changed its name to Quince Therapeutics, Inc ("Quince" or the "Company"). The Company was incorporated in the State of Delaware in June 2012 and is headquartered in South San Francisco, California.

From inception, the Company has been focused on novel therapeutic approaches to improve the lives of patients with major, unmet medical needs. The Company, previously named Cortexyme, Inc. (“Cortexyme”) was initially founded on the seminal discovery of the presence of Porphyromonas gingivalis ("P. gingivalis"), and its secreted toxic virulence factor proteases, called gingipains, in the relevant brain areas of both Alzheimer's and Parkinson's disease patients.

In May 2022, the Company completed the acquisition of Novosteo, Inc. ("Novosteo"), a Delaware corporation, a privately held biotechnology company focused on targeted therapeutics to treat rare skeletal diseases, bone fractures and injury. The acquisition of Novosteo, in 2022 (the "Novosteo Acquisition"), and the addition of new executive management allowed us to strategically shift focus and prioritize the internal development of our innovative bone-targeting drug platform and lead preclinical compound NOV004 for development for rare skeletal diseases, bone fractures, and injury. Following the Novosteo Acquisition in August 2022, the Company changed the corporate name to Quince Therapeutics, Inc.. At that time, the Company also announced it intended to actively seek compelling clinical-stage assets available for in-licensing and acquisition to expand our development pipeline with a focus on acquiring, developing, and commercializing innovative therapeutics for patients suffering from debilitating and rare diseases.

On January 30, 2023, the Company announced that it intended to prioritize capital resources toward the expansion of its development pipeline through opportunistic in-licensing and acquisition of clinical-stage assets targeting debilitating and rare diseases. The Company also plans to out-license its bone-targeting drug platform and precision bone growth molecule NOV004 designed for accelerated fracture repair in patients with bone fractures and osteogenesis imperfecta.

On October 20, 2023, we completed our acquisition of EryDel S.p.A., (“EryDel”), a privately-held, late-stage biotechnology company (the “EryDel Acquisition”) with a Phase 3 lead asset, EryDex, that targets the treatment of a rare neurodegenerative disease, Ataxia-Telangiectasia ("A-T"), for which there are currently no approved treatments globally.

The EryDel Acquisition was completed pursuant to that certain Stock Purchase Agreement, dated as of July 21, 2023, (the “Purchase Agreement”), by and among the Company, EryDel, EryDel Italy, Inc., holders of EryDel capital stock and the managers of EryDel (the “EryDel Shareholders”) and Shareholder Representative Services LLC, a Colorado limited liability company solely in its capacity as the representative, agent and attorney-in-fact of the EryDel Shareholders. Pursuant to the terms of the Purchase Agreement, the Company issued 6,525,315 shares of common stock of the Company to the EryDel Shareholders. Up to an additional 725,037 shares of the Company’s common stock may be issued to the EryDel Shareholders upon the first anniversary of the closing of the EryDel Acquisition. The EryDel Shareholders have a contingent right to receive up to an aggregate of $485,000,000 in potential cash payments, comprised of up to $5,000,000 upon the achievement of a specified development milestone, $25,000,000 at new drug application ("NDA") acceptance by the U.S. Food and Drug Administration ("FDA"), up to $60,000,000 upon the achievement of specified approval milestones, and up to $395,000,000 upon the achievement of specified on market and sales milestones, with no royalties paid to EryDel. Refer to Note 13 Subsequent Events for additional details.

Novosteo, Inc. Acquisition

On May 9, 2022, the Company entered into an Agreement and Plan of Merger and Reorganization (the “Merger Agreement”) with Novosteo, Quince Merger Sub I, Inc., a Delaware corporation and a wholly owned subsidiary of the Company, Quince Merger Sub II, LLC, a Delaware limited liability company and a wholly owned subsidiary of Company, Novosteo, and Fortis Advisors LLC, a Delaware limited liability company, solely in its capacity as the securityholders’ representative. The transaction closed on May 19, 2022. Pursuant to the terms of the Merger Agreement, at the closing of the Novosteo Acquisition, each outstanding share of capital stock of Novosteo was automatically cancelled and converted into the right to receive 0.0911 shares of common stock, par value $0.001 per share, of the Company. The Company issued 5,520,000 shares and assumed 507,108 outstanding Novosteo options after conversion with the awards, retaining the same vesting and other terms and conditions as in effect immediately prior to consummation of the Novosteo Acquisition.

Pursuant to the Merger Agreement, upon the terms and subject to the conditions set forth therein, Merger Sub I merged with and into Novosteo (the “First Merger”), with Novosteo as the surviving entity in the First Merger (the “First Step Surviving Corporation”). Immediately following the First Merger, the First Step Surviving Corporation merged with and into Merger Sub II, with Merger Sub II surviving the Novosteo Acquisition. Merger Sub II was renamed Novosteo, LLC and is a wholly-owned single member limited liability corporation. Novosteo, LLC has a wholly owned subsidiary in Australia, Novosteo Pty Ltd.

Sale of Legacy Portfolio

On January 27, 2023, the Company sold its legacy small molecule protease inhibitor portfolio, including COR588, COR388, COR852, and COR803, pursuant to an asset purchase agreement with Lighthouse Pharmaceuticals, Inc., (the "Purchaser" or “Lighthouse”) an entity co-founded by Casey Lynch, former chief executive officer of Quince’s predecessor company Cortexyme, Inc.

Upon the consummation of the transaction, the Company received shares of common stock of Purchaser (“Common Stock”) equal to seven and a half percent (7.5%) of the currently issued and outstanding Common Stock. The issuance is governed by a Stock Issuance Agreement entered into by the Company and the Purchaser on January 27, 2023 (the “Stock Agreement”).

Pursuant to the terms of the asset purchase agreement, the Company is eligible to receive milestone payments up to $150 million on a product by product basis for the achievement of certain regulatory approvals and global net sales thresholds. Additionally, the Company is eligible to receive certain sales-based royalty payments on a product by product basis, ranging from high single-digit to mid-teens of annual net sales related to the two existing clinical stage programs, and low single-digit royalties for the preclinical programs, and certain sublicense income on a product by product basis, either in addition to milestone payments and royalties prior to Phase 2 initiation for COR588 or COR388, or in lieu of milestones payments and royalties after initiation of Phase 2 for COR588 or COR388 or for the preclinical programs.

Liquidity and Capital Resources

The Company has incurred losses and negative cash flows from operations since inception and expects to continue to generate operating losses for the foreseeable future. As of September 30, 2023, the Company had an accumulated deficit of $310.8 million. Since inception through September 30, 2023, the Company has funded operations primarily with the net proceeds from the issuance of convertible promissory notes, from the issuance of redeemable convertible preferred stock, from the net proceeds from the Company’s initial public offering (the “IPO”), a private investment in public equity transaction (“PIPE Financing”), and an at-the-market offering under an open market sales agreement. As of September 30, 2023, the Company had cash, cash equivalents, and short-term investments of $83.2 million, which it believes will be sufficient to fund its planned operations for a period of at least 12 months from the date of the issuance of the accompanying unaudited consolidated financial statements. The Company had no long-term investments as of September 30, 2023.

Management expects to incur additional losses in the future to fund the Company's operations, advance clinical trials, and conduct product research and development and may need to raise additional capital to fully implement its business plan. The Company may raise additional capital through the issuance of equity securities, debt financings or other sources including out-licensing or partnerships, in order to further implement its business plan. However, if such financing is not available when needed and at adequate levels, the Company will need to reevaluate its operating plan and may be required to delay the development of in-licensed or acquired clinical stage assets accordingly.

Note 2. Summary of Significant Accounting Policies

Basis of Consolidation

The accompanying condensed consolidated financial statements include the accounts of Quince Therapeutics, Inc. and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) for interim financial information and pursuant to the instructions of the SEC on Form 10-Q and Article 8 of Regulation S-X of the SEC. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the management’s opinion, all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation of the results of operations and cash flows for the periods presented have been included.

The condensed consolidated balance sheet as of September 30, 2023, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2023 and 2022, the condensed consolidated statements of stockholders' equity for the three and nine months ended September 30, 2023 and 2022, the condensed consolidated statements of cash flows for the nine months ended September 30, 2023 and 2022, and the financial data and other financial information disclosed in the notes to the condensed consolidated financial statements are unaudited. These financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2022 included in the Company's Form 10-K filed with the SEC on March 15, 2023. The results of operations for the three and nine months ended September 30, 2023 are not necessarily indicative of the results to be expected for the year ending December 31, 2023 or for any other future annual or interim period.

Risks and Uncertainties

The Company's future results of operations involve a number of risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, uncertainty of results of clinical trials and reaching milestones, uncertainty of regulatory approval of the Company's potential drug candidates, uncertainty of market acceptance of the Company's drug candidates, competition from substitute products and larger companies, securing and protecting proprietary technology, strategic relationships and dependence on key individuals and sole source suppliers. The Company's drug candidates will require approvals from the U.S. Food and Drug Administration ("FDA") and comparable foreign regulatory agencies prior to commercial sales in their respective jurisdictions. There can be no assurance that any drug candidate will receive the necessary approvals.

Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, and expenses, as well as related disclosure of contingent assets and liabilities. The most significant estimates used in the Company's consolidated financial statements relate to the determination of the fair value of stock-based awards and other issuances, determination of the fair value of identifiable assets and liabilities in connection with the acquisition of Novosteo, Inc., including associated intangible assets and goodwill, accruals for research and development costs, useful lives of long-lived assets, stock-based compensation and related assumptions, the incremental borrowing rate for leases and income tax uncertainties, including a valuation allowance for deferred tax assets, eligibility of expenses for the Australia research and development refundable tax credits, impairment of intangible assets or goodwill, collectability of note receivable; and contingencies. The Company bases its estimates on historical experience and on various other market specific and other relevant assumptions that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ materially from the Company's estimates.

Foreign Currency Translation and Transactions

In April 2021, the Company established a wholly owned subsidiary in Australia, Cortexyme Australia, Pty Ltd. In addition, Novosteo, LLC has a wholly owned subsidiary in Australia, Novosteo Pty Ltd. The functional currency of two of the Company's wholly-owned subsidiaries is the Australian Dollar. Its financial results and financial position are translated into U.S. dollars using exchange rates at balance sheet dates for assets and liabilities and using average exchange rates for income and expenses. The resulting translation differences are presented as a separate component of accumulated other comprehensive income (loss), as a separate component of equity.

Foreign currency transactions are translated into the functional currencies using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses, resulting from the settlement of such transactions and from the re-measurement of monetary assets and liabilities denominated in foreign currencies using exchange rates at balance sheet date and non-monetary assets and liabilities using historical exchange rates, are recognized in the condensed consolidated statements of operations and comprehensive loss.

Significant Accounting Policies

There have been no significant changes to the accounting policies during the nine months ended September 30, 2023, as compared to the significant accounting policies described in our Annual Report on Form 10-K.

Business Combinations

The Company accounts for business combinations using the acquisition method pursuant to the Financial Accounting Standards Board (the "FASB") Accounting Standards Codification ("ASC") Topic 805. This method requires, among other things,

that results of operations of acquired companies are included in the Company's financial results beginning on the respective acquisition dates, and that identifiable assets acquired and liabilities assumed are recognized at fair value as of the acquisition date. Intangible assets acquired in a business combination are recorded at fair value using one of three valuation approaches, the income approach, the market approach or the cost approach. The Company reviewed the three valuation approaches and determined the income approach was the most appropriate model to approximate fair value for the Novosteo Acquisition. The income approach model requires assumptions about the timing and amount of future net cash flows, the cost of capital and terminal values from the perspective of a market participant. Any excess of the fair value of consideration transferred (the "Purchase Price") over the fair values of the net assets acquired is recognized as goodwill. The fair value of identifiable assets acquired and liabilities assumed in certain cases may be subject to revision based on the final determination of fair value during a period of time not to exceed 12 months from the acquisition date. Legal costs, due diligence costs, business valuation costs and all other acquisition-related costs are expensed when incurred.

Assets Held for Sale

Assets held for sale represent lab equipment that have met the criteria of "held for sale" accounting, as specified by Accounting Standards Codification ("ASC") 360, "Long-lived Assets." As of September 30, 2023, there were $0.1 million of lab equipment that are recorded as assets held for sale. The effect of suspending depreciation on the equipment held for sale is immaterial to the results of operations. The assets held for sale are being marketed for sale and it is the Company's intention to complete the sales of these assets within the upcoming year.

Intangible Assets

Intangible assets with a definite useful life are amortized on a straight-line basis over the estimated useful life of the related assets. Intangible assets with an indefinite useful life are not amortized. Intangible assets acquired in a business combination or an acquisition that are used in research and development activities (regardless of whether they have an alternative future use) shall be considered indefinite lived until the completion or abandonment of the associated research and development efforts. Intangible assets acquired in a business combination are initially recorded at fair value. During the period that those assets are considered indefinite lived, they shall not be amortized but shall be tested for impairment. Once the research and development efforts are completed or abandoned, the entity shall determine the useful life of the assets. An intangible asset shall be tested for impairment annually and more frequently if events or changes in circumstances indicate that it is more likely than not that the asset is impaired The Company first assesses qualitative factors to determine whether it is more likely than not that the fair value of the intangible asset is less than its carrying amount, If that is the case, the Company performs a quantitative impairment test, and, if the carrying amount of the Company exceeds its fair value, then the Company will recognize an impairment charge for the amount by which its carrying amount exceeds its fair value, not to exceed the carrying amount of the intangible asset. Qualitative factors to be considered include but are not limited to:

- Cost factors such as increases in raw materials, labor, or other costs that have a negative effect on future expected earnings and cash flows
- Legal/regulatory factors or progress and results of clinical trials
- Other relevant entity-specific events such as changes in management, key personnel, strategy, or customers; contemplation of bankruptcy; or litigation that could affect significant inputs used to determine the fair value of the indefinite-lived intangible asset
- Industry and market considerations such as a deterioration in the environment in which an entity operates, an increased competitive environment
- Macroeconomic conditions such as deterioration in general economic conditions, limitations on accessing capital, fluctuations in foreign exchange rates, or other developments in equity and credit markets that could affect significant inputs used to determine the fair value of the indefinite-lived intangible asset

Goodwill

Goodwill represents the excess of the purchase price over the fair value of the net assets acquired as of the acquisition date. Goodwill has an indefinite useful life and is not amortized. The Company reviews its goodwill for impairment at least annually or whenever events or changes in circumstances indicate that the carrying amount of the Company may exceed its fair value. The Company first assesses qualitative factors to determine whether it is more likely than not that the fair value of the Company is less than its carrying amount, including goodwill. If that is the case, the Company performs a quantitative impairment test, and, if the carrying amount of the Company exceeds its fair value, then the Company will recognize an impairment charge for the amount by which its carrying amount exceeds its fair value, not to exceed the carrying amount of the goodwill.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase to be cash and cash equivalents. Cash equivalents, which consist of amounts invested in money market funds, are stated at fair value. There are no unrealized gains or losses on the money market funds for the periods presented.

Investments

The Company's marketable securities primarily consist of U.S. Government and corporate debt securities. The Company classifies its marketable securities as available-for-sale and records such assets at estimated fair value in the condensed balance sheets, with unrealized gains and losses, if any, reported as a component of other comprehensive income (loss) within the condensed statements of operations and comprehensive loss and as a separate component of stockholders' equity. The Company classifies marketable securities with remaining maturities greater than one year as current assets because such marketable securities are available to fund the Company's current operations. Realized gains and losses are calculated on the specific identification method and recorded as interest income. There were no realized gains and losses during the periods presented.

At each balance sheet date, the Company assesses available-for-sale debt securities in an unrealized loss position to determine whether the unrealized loss or any potential credit losses should be recognized in net income (loss). For available-for-sale debt securities in an unrealized loss position, the Company first assesses whether it intends to sell, or it is more likely than not that it will be required to sell, the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the security's amortized cost basis is written down to fair value through net income (loss). For available-for-sale securities that do not meet the aforementioned criteria, the Company evaluates whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, the Company considers the severity of the impairment, any changes in interest rates, underlying credit ratings and forecasted recovery, among other factors. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded as an allowance in interest income. There have been no impairment or credit losses recognized during the periods presented.

The Company excludes the applicable accrued interest from both the fair value and amortized costs basis of the Company's available-for-sale securities for the purpose of identifying and measuring an impairment. Accrued interest receivable on available-for-sale securities is recorded within prepaid and other assets on the balance sheets. The Company made an accounting policy election to (1) not measure an allowance for credit loss for accrued interest receivable, and (2) to write-off any uncollectible accrued interest receivable as a reversal of interest income in a timely manner, which the Company considers to be in the period in which it determines the accrued interest will not be collected.

See Note 3 (Fair Value Measurements) for further information.

Fair Value Measurements

The fair value of the Company's financial instruments reflects the amounts that the Company estimates that it would receive in connection with the sale of an asset or pay in connection with the transfer of a liability in an orderly transaction between market participants at the measurement date (exit price). The Company discloses and recognizes the fair value of its assets and liabilities using a hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to valuations based upon unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to valuations based upon unobservable inputs that are significant to the valuation (Level 3 measurements). The guidance establishes three levels of the fair value hierarchy as follows:

Level 1 - Inputs that reflect unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date;

Level 2 - Inputs other than quoted prices that are observable for the assets or liability either directly or indirectly, including inputs in markets that are not considered to be active;

Level 3 - Inputs that are unobservable. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability. The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period.

Equity Investments without Readily Determinable Fair Values

Equity investments without readily determinable fair values include ownership rights that either (i) do not meet the definition of in-substance common stock or (ii) do not provide the Company with control or significant influence and these investments do not have readily determinable fair values. Equity investments without readily determinable fair values are recorded at cost, less any impairment, and adjusted for subsequent observable price changes as of the date that an observable transaction takes place and are recorded in other income (expense), net (See Note 4).

Recent Accounting Pronouncements Adopted

Financial Instruments—Credit Losses: In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses* (Topic 326): Measurement of Credit Losses on Financial Instruments which amends the principles around the recognition of credit losses by mandating entities incorporate an estimate of current expected credit losses when determining the value of certain assets. The guidance also amends reporting around allowances for credit losses on available-for-sale marketable securities. In November 2019, the FASB issued ASU 2019-10, Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815) and Leases (Topic 842): Effective Dates, which established that a one-time determination of the effective date for ASU 2016-13 would be based on the Company's SEC reporting status as of November 15, 2019. The Company was a "smaller reporting company" as defined by Item 10 of Regulation S-K, and therefore, ASU 2016-13 is effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. This guidance helps to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. To achieve this objective, the amendments in Topic 326 replace the incurred loss impairment methodology in current U.S. GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The Company has adopted the new guidance as of January 1, 2023, and it did not have a material impact on its financial statements and related disclosures.

Recent Accounting Pronouncements Not Yet Adopted

The following are new accounting pronouncements that the Company is evaluating for future impacts on its financial statements:

Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions (ASC 820); In June 2022, the FASB issued ASU No. 2022-03, "*Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions*." This ASU clarifies that a contractual restriction on the sale of equity security should not be considered in measuring the fair value. In addition, the ASU requires specific disclosures related to contractual sale restrictions. The ASU is effective in January 2024 under a prospective approach. Early adoption is permitted. Adoption of this ASU is not expected to have a material impact on the Company's condensed consolidated financial statements.

Note 3. Fair Value Measurements

The Company measures and reports its cash equivalents and investments at fair value.

Money market funds are measured at fair value on a recurring basis using quoted prices and are classified as Level 1. Investments are measured at fair value based on inputs other than quoted prices that are derived from observable market data and are classified as Level 2 inputs.

Financial assets and liabilities subject to fair value measurements on a recurring basis and the level of inputs used in such measurements by major security type as of September 30, 2023 and December 31, 2022 are presented in the following tables (in thousands):

	Fair Value Measurements at September 30, 2023			
	Total	Level 1	Level 2	Level 3
Money market funds	$ 12,285	$ 12,285	$ —	$ —
Certificates of Deposit	1,465	—	1,465	—
Government and agency notes	68,666	—	68,666	—
Total	$ 82,416	$ 12,285	$ 70,131	$ —

	Fair Value Measurements at December 31, 2022			
	Total	Level 1	Level 2	Level 3
Money market funds	$ 10,988	$ 10,988	$ —	$ —
Certificates of Deposit	6,102	—	6,102	—
Repurchase Agreements	9,000	—	9,000	—
Corporate notes	12,411	—	12,411	—
Government and agency notes	50,766	—	50,766	—
Municipal notes	506	—	506	—
Total	$ 89,773	$ 10,988	$ 78,785	$ —

The following table summarizes the available-for-sale securities (in thousands):

	Fair Value Measurements at September 30, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds	$ 12,285	$ —	$ —	$ 12,285
Certificates of Deposit	1,480	—	(15)	1,465
Government and agency notes	68,712	4	(50)	68,666
Total cash equivalents and investments	$ 82,477	$ 4	$ (65)	$ 82,416
Classified as:				
Cash equivalents (original maturities within 90 days)				$ 20,823
Short-term investments (maturities within one year)				61,593
Total cash equivalents and investments				$ 82,416

	Fair Value Measurements at December 31, 2022			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds	$ 10,988	$ —	$ —	$ 10,988
Certificates of Deposit	6,237	1	(136)	6,102
Repurchase Agreements	9,000	—	—	9,000
Corporate notes	12,575	—	(164)	12,411
Government and agency notes	51,020	4	(258)	50,766
Municipal notes	510	—	(4)	506
Total cash equivalents and investments	$ 90,330	$ 5	$ (562)	$ 89,773
Classified as:				
Cash equivalents (original maturities within 90 days)				$ 40,593
Short-term investments (maturities within one year)				45,602
Long-term investments (maturities beyond one year)				3,578
Total cash equivalents and investments				$ 89,773

As of September 30, 2023, the remaining contractual maturities of available-for-sale securities was approximately 3 months. There have been no significant realized gains or losses on available-for-sale securities for the periods presented. The Company records its available-for-sale debt securities at fair value, with changes in fair value reported as a component of accumulated other comprehensive income (loss). We periodically assess our investment in available-for-sale securities for impairment losses and credit losses. The amount of credit losses is determined by comparing the difference between the present value of future cash flows expected to be collected on these securities and the amortized cost. Factors considered in assessing credit losses include the position in the capital structure, vintage and amount of collateral, delinquency rates, current credit support, and geographic concentration. There have been no impairment and credit losses related to available-for-sale securities for the three and nine months ended September 30, 2023 and 2022.

The table below summarizes the unrealized losses of the Company's investments in debt securities measured at fair value as of September 30, 2023 (in thousands):

	Less than twelve months		Twelve months or greater		Total	
	Fair value	Gross unrealized loss	Fair value	Gross unrealized loss	Fair value	Gross unrealized loss
Certificates of deposit	$ —	$ —	$ 1,465	$ (15)	$ 1,465	$ (15)
Government and agency notes	22,662	(5)	3,686	(45)	26,348	(50)
Total cash equivalents and investments	$ 22,662	$ (5)	$ 5,151	$ (60)	$ 27,813	$ (65)

The investments are classified as available-for-sale securities. At September 30, 2023 and December 31, 2022, the balance in the Company’s accumulated other comprehensive income (loss) was comprised primarily of activity related to the Company’s available-for-sale securities. There were no realized gains or losses recognized on the sale or maturity of available-for-sale securities for the three and nine months ended September 30, 2023 and as a result, the Company did not reclassify any amounts out of accumulated other comprehensive income for the quarter.

There were no transfers between Levels 1, 2 or 3 for the period presented.

The table below summarizes the contractual maturities of the Company's investments in debt securities measured at fair value as of September 30, 2023 (in thousands):

	Maturities by Period				
	Total	Less Than 1 Year	1-5 Years	6-10 Years	More Than 10 Years
Fair value of debt securities	$ 61,593	$ 61,593	$ —	$ —	$ —

Note 4. Cash, Cash Equivalents and Investments

The following tables categorize the fair values of cash, cash equivalents, short-term investments and long-term investments measured at fair value on a recurring basis on our balance sheets (in thousands):

	September 30, 2023	December 31, 2022
Cash and cash equivalents:		
Cash	$ 809	$ 3,986
Money market funds	12,285	10,988
Repurchase agreements	—	9,000
Government and agency notes	8,538	20,605
Total cash and cash equivalents	$ 21,632	$ 44,579
Short-term investments:		
Certificates of deposit	$ 1,465	$ 5,390
Municipal notes	—	506
Corporate notes	—	12,411
Government and agency notes	60,128	27,295
Total short-term investments	$ 61,593	$ 45,602
Long-term investments		
Certificates of deposit	$ —	$ 712
Government and agency notes	—	2,866
Total long-term investments	$ —	$ 3,578

Equity investments without readily determinable fair values assessed under the measurement alternative

Equity investments without readily determinable fair value include ownership rights that either (i) do not meet the definition of in-substance common stock or (ii) do not provide the Company with control or significant influence and these investments do not have readily determinable fair values.

During the nine months ended September 30, 2023, the Company received approximately $78,000 in equity investments without readily determinable fair values of Lighthouse in exchange for the Legacy Assets. As of September 30, 2023, the Company has not recorded any cumulative upward adjustments or cumulative impairments for its equity investments without readily determinable fair values.

Note 5. Balance Sheet Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	September 30, 2023	December 31, 2022
Prepaid expenses	$ 270	$ 223
Prepaid insurance	1,037	977
Prepaid research and development expenses	49	1,088
Australia research and development refundable tax credit	—	1,003
Other current assets	92	276
Total prepaid expenses and other current assets	$ 1,448	$ 3,567

Cortexyme Australia, Pty, Ltd is eligible to obtain a cash refund from the Australian Taxation Office for eligible R&D expenditures under the Australian R&D Tax Incentive Program (the “Australian Tax Incentive”). The Australian Tax Incentive is recognized as a reduction to R&D expense when there is reasonable assurance that the relevant expenditure has been incurred, the amount can be reliably measured and the Australian Tax Incentive will be received. The Company received a refundable tax credit of $0.5 million in the second quarter of 2023, which reduced prepaid expenses and other current assets by $0.5 million as of June 30, 2023. The Company recognized reductions to R&D expense of $0 for the three and nine months ended September 30, 2023 and $0.1 million and $0.5 million reductions to R&D expense for the three and nine months ended September 30, 2022.

Novosteo Pty, Ltd is eligible to obtain a cash refund from the Australian Taxation Office for eligible R&D expenditures under the Australian Tax Incentive as well. The Company received a refundable tax credit of $0.5 million in the first quarter of 2023, which reduced prepaid expenses and other current assets by $0.5 million as of March 31, 2023.

Notes Receivable

Notes receivables consist of the following (in thousands):

	September 30, 2023	December 31, 2022
Notes receivable	500	—
Total Notes receivable	$ 500	$ —

On August 30, 2023, EryDel Italy, Inc., an indirect wholly owned subsidiary of the Company, entered into that certain promissory note, (the “Promissory Note”) with EryDel S.p.A. (“EryDel”), pursuant to which EryDel Italy, Inc. promised to make advances to EryDel of up to $1.0 million.

Under the terms of the Promissory Note, the principal amount of the note shall be made available in two tranches, an initial tranche, in an aggregate amount of $500,000, with an interest rate of 5.07% per annum, and a second tranche, up to an aggregate amount of $500,000, with an annual interest rate equal to Applicable Federal Rate for Annual Compounding Short-Term Debt Instruments as at the funding date of such tranche, to be funded to EryDel during the period commencing September 1, 2023 to October 31, 2023. The first tranche was made during the three months ended September 30, 2023. Interest receivable as of September 30, 2023 was approximately $1,300.

The Promissory Note will mature on July 1, 2024, provided that, subject to certain conditions, in the event that the closing date occurs under the Stock Purchase Agreement on or before December 31, 2023, or the Stock Purchase Agreement is terminated for any reason other than by the Company in certain specified circumstances, all obligations of EryDel and EryDel Italy, Inc. under the

Promissory Note shall be deemed to be paid and discharged in full, all unfunded commitments of EryDel Italy, Inc. to make advances under the Promissory Note shall be terminated, and all other obligations of EryDel shall be deemed terminated.

For additional details, refer to Note 13 Subsequent Events.

Assets Held for Sale

Assets held for sale consist of the following (in thousands):

	September 30, 2023	December 31, 2022
Assets held for sale	$ 82	$ —
Total assets held for sale	$ 82	$ —

In response to the reprioritization of its pipeline following the decision to discontinue internal development of NOV004 and to pursue out-licensing opportunities the Company reclassified the equipment on consignment of $0.1 million to Assets held for sale.

Property and Equipment, Net

Property and equipment, net consist of the following (in thousands):

	September 30, 2023	December 31, 2022
Computer equipment	$ 18	$ 18
Lab equipment	—	415
Finance lease right of use assets	—	124
Leasehold improvement	—	21
Less: accumulated amortization and depreciation	(13)	(185)
Property and equipment, net	$ 5	$ 393

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

	September 30, 2023	December 31, 2022
Personnel expenses	$ 1,366	$ 1,130
Professional fees	225	234
Research and development expenses	41	497
Current portion of operating lease liabilities	61	377
Current portion of finance lease liability	—	76
Other	151	185
Total accrued expenses and other current liabilities	$ 1,844	$ 2,499

Below is the severance accrual activity included in the personnel expenses in the above table related to a cost reduction program during the period ended September 30, 2023 (in thousands):

	For the Nine Months Ended September 30, 2023
Beginning accrued severance	$ —
Incurred during the period	770
Severance paid during the period	(309)
Ending accrued severance	461

In response to the reprioritization of the Company's pipeline following the decision to discontinue internal development of NOV004 and to pursue out-licensing opportunities, the Board approved a cost reduction program to reorganize operations and allow continued support for the needs of the business. Under the cost reduction program, the Company lowered headcount through a reduction in workforce. The Company recognized the severance and related expenses over the requisite employment obligation period. The reduction in force was completed in April 2023.

On August 4, 2023, the Company entered into a transition and separation agreement with Karen Smith, M.D., Ph.D., (the “Separation Agreement”) in connection with Dr. Smith’s transition and departure from the Company as the Company's Chief Medical Officer, effective as of September 1, 2023. Pursuant to the Separation Agreement, the Company is required to pay cash severance, equal to her annual salary, in the aggregate amount of $475,000, paid on regular payroll schedule through the third quarter of 2024. Additionally, pursuant to the Separation Agreement, the Company paid an additional cash bonus severance payment equal to 100% of Dr. Smith’s target annual bonus opportunity for 2023 on a prorated basis, an additional cash severance payment equal to 12 months’ of the monthly premiums for health care continuation benefits, and provided for 50% accelerated vesting with respect to Dr. Smith’s equity award. The acceleration of 612,141 options and 54,757 RSAs resulted in a stock-based compensation expense of approximately $140,000.

Note 6. Leases

Real Estate Operating Leases

In June 2022, the Company entered into a Sublease Agreement to rent office space in South San Francisco, California. The Sublease Agreement commenced on June 18, 2022 and ends on November 30, 2023. The total payments under the term of the lease are expected to be approximately $271,000. The Company paid a security deposit of $17,000 which is included in Prepaid Expenses and Other Current Assets on the September 30, 2023 condensed consolidated balance sheets. At the commencement of the lease, the Company recorded an operating lease right of use asset and liability of $256,000. On October 31, 2023, the Company signed a lease agreement for a smaller office space in South San Francisco, California. The total payments under the new lease are expected to be approximately $22,000 for the year. The lease will commence on November 30, 2023 and end on November 30, 2024.

In October 2022, the Company entered into a lease agreement to rent space in West Lafayette, Indiana. The lease agreement amended the original lease to transfer liability to the Company due to the Novosteo Acquisition. The lease agreement is for 15 months, which commenced on October 1, 2022 and ends on December 31, 2023. The total payments under the term of the lease are expected to be approximately $151,000. At the commencement of the lease, the Company recorded an operating lease right of use asset and liability of $145,000.

In December 2022, the Company entered into an amendment to the lease agreement of the rental space in West Lafayette to rent additional space in the same facility under the same terms as its existing facility lease except the terms of payment. Under the terms of the amendment, the Company will pay rent monthly for the additional space. The Company recorded an operating lease right of use asset and liability of $10,000.

In February 2023, as a result of the decision to discontinue internal development of NOV004 and to pursue out-licensing opportunities, the Company entered into a sublease agreement as the lessor for the majority of the West Lafayette facility. The lease commenced on March 17, 2023 and ends on December 31, 2023. The sublessee paid the Company a security deposit of $6,000 which is included in Accrued expenses and other current liabilities on the September 30, 2023 condensed consolidated balance sheets. Under the terms of the sublease, the Company is entitled to receive a total rental income that is expected to offset rent expense of $57,000. As a result of this decision and the sublease agreement, the Company recorded an impairment loss of approximately $66,000 which is included in other expense, net per statements of operations and comprehensive loss for the nine months ended September 30, 2023 condensed consolidated statement of operations and comprehensive loss.

The Company recognizes lease expense on a straight-line basis over the term of its operating lease. As of September 30, 2023, total future rent expense from all real estate operating leases of $48,000 will be recognized over the remaining term of 2 to 3 months on a straight-line basis over the respective lease period.

Clinical Equipment Financing Lease

As part of the Novosteo Acquisition, the Company acquired a financing lease for certain lab equipment. The Company recognizes the depreciation expense in research and development expenses in the condensed consolidated statements of operations and comprehensive loss and recognizes expense on a straight-line basis starting when the equipment is placed into service until the end of

the remaining contract term of 18 months. Amortization expense of the financing lease right of use asset for the nine months ended September 30, 2023 was $6,000.

In February 2023, as a result of the decision to discontinue internal development of NOV004 and to pursue out-licensing opportunities, the Company exercised its purchase option for the financed equipment in order to resell and this equipment is currently held on consignment and is included in Assets held for sale on the September 30, 2023 condensed consolidated balance sheets. As a result of this action, the Company reduced the Finance lease ROU asset and Finance lease liability by approximately $70,000.

Supplemental balance sheet information related to leases as follows (in thousands except lease terms and discount rates):

	September 30, 2023	December 31, 2022
Operating lease right of use asset, net	$ 48	$ 291
Short-term operating lease liability	61	377
	$ 61	$ 377
Finance lease right of use asset	—	124
Finance lease accumulated amortization	—	(50)
Total finance lease right of use asset, net	$ —	$ 74
Weighted average remaining lease term		
Operating leases	0.2 years	0.9 years
Finance leases	—	1.0 year
Weighted average discount rate		
Operating leases	6.70%	5.71%
Finance leases	—%	4.45%

Year ended December 31,	**Operating Lease**	**Operating Lease**
Year ended December 31, 2023 (excluding the nine months ended September 30, 2023)	$ 62	$ 388
Total lease payments	62	388
Less: imputed interest	(1)	(11)
Total remaining lease liability	$ 61	$ 377

Note 7. Stock-Based Compensation

The Company operates three stock plans as of September 30, 2023.

- 2019 Equity Incentive Plan (Quince)
- 2019 Equity Incentive Plan (Novosteo)
- 2022 Inducement Plan (Quince)

2019 Equity Incentive Plan (Quince)

On December 4, 2014, the Company's stockholders approved the 2014 Stock Plan ("2014 Plan"), and on April 25, 2019 amended, restated and re-named the 2014 Plan as the 2019 Equity Incentive Plan (the "Quince 2019 Plan"), which became effective as of May 7, 2019, the day prior to the effectiveness of the registration statement filed in connection with the IPO. The remaining shares available for issuance under the 2014 Plan were added to the shares reserved for issuance under the Quince 2019 Plan.

The Quince 2019 Plan provides for the grant of stock options (including incentive stock options and non-qualified stock options), stock appreciation rights, restricted stock, RSUs, performance units, and performance shares to the Company's employees, directors, and consultants. As of September 30, 2023, the maximum aggregate number of shares that remain available for issuance under the Quince 2019 Plan is 10,036,489 shares of the Company's common stock. In addition, the number of shares available for issuance under the Quince 2019 Plan will be annually increased on the first day of each fiscal years beginning with fiscal 2020, by an amount equal to the least of (i) 2,146,354 shares of common stock; (ii) 4% of the outstanding shares of its common stock as of the last day of its immediately preceding fiscal year; and (iii) such other amount as the Board may determine.

The Quince 2019 Plan may be amended, suspended or terminated by the Board at any time, provided such action does not impair the existing rights of any participant, subject to stockholder approval of any amendment to the Quince 2019 Plan as required by applicable law or listing requirements. Unless sooner terminated by the Board, the Quince 2019 Plan will automatically terminate on April 23, 2029.

As of September 30, 2023, the Company had 4,964,784 shares available for future issuance under the Quince 2019 Plan.

Stock Options

Activity for service-based stock options under the Quince 2019 Plan is as follows:

	Number of Options and Unvested Shares	Weighted Average Exercise Price	Weighted average remaining contractual life (years)	Aggregate intrinsic value
				(In thousands)
Balance at December 31, 2022	**3,319,711**	$ 16.07	4.77	$ 65
Options granted	2,162,958	1.04	—	—
Options exercised	(258,705)	0.42	—	240
Options cancelled / forfeited	(1,915,786)	18.35	—	—
Balance at September 30, 2023	**3,308,178**	$ 6.15	8.15	$ 245
Options vested and expected to vest as of September 30, 2023	3,308,178	6.15	8.15	245
Options exercisable as of September 30, 2023	1,122,154	$ 13.46	6.56	$ 61

For the three and nine months ended September 30, 2023, the Company recognized stock-based compensation expense of $615,000 and $1,993,000, respectively, related to options granted to employees and non-employees. The compensation expense is allocated on a departmental basis, based on the classification of the option holder. No income tax benefits have been recognized in the condensed consolidated statement of operations and comprehensive loss for stock-based compensation arrangements. As of September 30, 2023, total unamortized employee stock-based compensation was $3.8 million, which is expected to be recognized over the remaining estimated vesting period of 2.37 years.

Performance Stock Options ("PSOs")

There was no activity or balance of any PSOs from the 2019 plan for the nine months ended September 30, 2023. For the three and nine months ended September 30, 2023, the Company recognized stock-based compensation expense of $0 related to these PSOs. For the three and nine months ended September 30, 2022, the Company recognized stock-based compensation expense of $0 and $2,044,000, respectively, related to these PSOs. As of September 30, 2023 and December 31, 2022, there was no remaining unamortized stock-based compensation related to PSOs.

Restricted Stock Units ("RSUs")

The following table summarizes activity under the Company's RSUs from the Quince 2019 Plan and related information:

	Restricted Stock Units Outstanding	
	Number of Shares	Weighted Average Grant Date Fair Value
Unvested - December 31, 2022	**30,876**	$ 4.30
RSUs granted	—	—
RSUs vested	(8,713)	4.30
RSUs cancelled	(19,188)	4.30
Unvested - September 30, 2023	**2,975**	**$ 4.30**

The fair value of the RSUs is determined on the grant date based on the fair value of the Company's common stock. The fair value of the RSUs is recognized as expense ratably over the vesting period of two years. The total grant date fair value of the RSUs vested during the three and nine months ended September 30, 2023 was $6,400 and $37,500, respectively. The aggregate intrinsic value of the shares of the RSUs vested during the three and nine months ended September 30, 2023 was $2,000 and $9,900, respectively.

For the three and nine months ended September 30, 2023, the Company recognized stock-based compensation expense of $6,000 and $31,000 respectively, related to these RSUs. As of September 30, 2023, total unamortized stock-based compensation related to RSUs was $11,000, which is expected to be recognized over the remaining estimated vesting period of 0.42 years.

2019 Equity Incentive Plan (Novosteo)

On May 19, 2022, in accordance with the term of the Merger Agreement, the Company assumed the 2019 Novosteo, Inc Equity Incentive Plan (the "2019 Novosteo Plan"). The 2019 Novosteo Plan provides for the grant of stock options (including incentive stock options and non-qualified stock options), stock appreciation rights, restricted stock, RSUs, performance units, and performance shares to the Novosteo legacy employees. On the closing date, each outstanding Novosteo stock option granted under Novosteo's equity compensation plans was converted into a corresponding stock option with the number of shares underlying such option and the applicable exercise price adjusted based and adjusted into the right to purchase 0.0911 shares of common stock. Each such converted stock option will continue to be subject to substantially the same terms and conditions as applied to the corresponding Novosteo stock option prior to the Novosteo Acquisition. The maximum aggregate number of shares that may be issued under the 2019 Novosteo Plan is 544,985 shares of the Company's common stock.

The 2019 Novosteo Plan may be amended, suspended or terminated by the Board at any time, provided such action does not impair the existing rights of any participant, subject to stockholder approval of any amendment to the 2019 Novosteo Plan as required by applicable law or listing requirements. Unless sooner terminated by the Board, the 2019 Novosteo Plan will automatically terminate on May 20, 2029.

As of September 30, 2023, the Company had 143,022 shares available for future issuance under the 2019 Novosteo Plan.

Activity for service-based stock options under the 2019 Novosteo Plan is as follows:

	Number of Options and Unvested Shares	Weighted Average Exercise Price	Weighted average remaining contractual life (years)	Aggregate intrinsic value
				(In thousands)
Balance at December 31, 2022	**503,105**	$ 0.55	9.23	$ 44
Options granted	—	—	—	—
Options exercised	(3,027)	0.55	—	3
Options cancelled / forfeited	(37,848)	0.55	—	—
Balance at September 30, 2023	**462,230**	$ 0.55	5.75	$ 263
Options vested and expected to vest as of September 30, 2023	462,230	0.55	5.75	263
Options exercisable as of September 30, 2023	219,190	0.55	4.58	125

For the three and nine months ended September 30, 2023, the Company recognized stock-based compensation expense of $96,000 and $226,000, respectively, related to options granted to employees and non-employees for the 2019 Novosteo plan. The compensation expense is allocated on a departmental basis, based on the classification of the option holder. No income tax benefits have been recognized in the condensed consolidated statement of operations and comprehensive loss for stock-based compensation arrangements. As of September 30, 2023, total unamortized employee stock-based compensation was $0.5 million, which is expected to be recognized over the remaining estimated vesting period of 2.48 years.

On May 19, 2022, in accordance with the term of the Merger Agreement, the Company assumed a number of restricted stock awards ("RSAs") agreements with certain employees. Each outstanding Novosteo RSA was converted into a corresponding RSA with the number of shares underlying such RSA adjusted into 0.0911 shares of common stock. Each such converted RSA will continue to be subject to substantially the same terms and conditions as applied to the corresponding Novosteo RSA prior to the Novosteo Acquisition.

Restricted Stock Awards ("RSAs")

	Restricted Stock Awards Outstanding	
	Number of Shares	Weighted Average Grant Date Fair Value
Unvested - December 31, 2022	**427,401**	$ 3.30
RSAs granted	—	—
RSAs vested	(164,008)	3.30
RSAs cancelled	(63,294)	3.30
Unvested - September 30, 2023	**200,099**	**$ 3.30**

For the three and nine months ended September 30, 2023, the Company recognized stock-based compensation expense of $167,000 and $415,000, respectively, related to restricted stock awards. The compensation expense is allocated on a departmental basis, based on the classification of the option holder. No income tax benefits have been recognized in the condensed consolidated statement of operations and comprehensive loss for stock-based compensation arrangements. As of September 30, 2023, total unamortized employee stock-based compensation was $0.6 million, which is expected to be recognized over the remaining estimated vesting period of 1.99 years.

2022 Inducement Plan

On May 9, 2022, the Board approved 4,000,000 shares of the Registrant's common stock that may be offered or issued under the Quince Therapeutics, Inc. 2022 Inducement Plan (the "2022 Inducement Plan"). The 2022 Inducement Plan was adopted by the independent members of the Board without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Listing Rules. In accordance with rule awards under those plans may only be made to an employee who has not previously been an employee or member of the Board or of any board of directors of any parent or subsidiary of the Company, or following a bona fide period of non-employment by the Company or a parent or subsidiary, if he or she is granted such award in connection with his or her commencement of employment with the Company or a subsidiary and such grant is an inducement material to his or her entering into employment with the Company or such subsidiary. The terms and conditions of the 2022 Inducement Plan are substantially similar to those of the Quince 2019 Plan.

As of September 30, 2023, the Company had 301,245 shares available for future issuance under the 2022 Inducement Plan.

Activity for service-based stock options under the 2022 Inducement Plan is as follows:

	Number of Options and Unvested Shares	Weighted Average Exercise Price	Weighted average remaining contractual life (years)	Aggregate intrinsic value
				(In thousands)
Balance at December 31, 2022	**3,742,255**	$ 2.98	9.39	$ —
Options granted	—	—	—	—
Options exercised	—	—	—	—
Options cancelled / forfeited	(43,500)	2.98	—	—
Balance at September 30, 2023	**3,698,755**	$ 2.98	5.52	$ —
Options vested and expected to vest as of September 30, 2023	3,698,755	2.98	5.52	—
Options exercisable as of September 30, 2023	1,673,844	2.98	4.11	—

For the three and nine months ended September 30, 2023, the Company recognized stock-based compensation expense of $447,000 and $1,469,000, respectively, related to options granted to employees and non-employees for the 2022 Inducement plan. The compensation expense is allocated on a departmental basis, based on the classification of the option holder. No income tax benefits have been recognized in the condensed consolidated statement of operations and comprehensive for stock-based compensation arrangements. As of September 30, 2023, total unamortized employee stock-based compensation was $3.5 million, which is expected to be recognized over the remaining estimated vesting period of 2.64 years.

Stock-Based Compensation Expense

The following table summarizes employee and non-employee stock-based compensation expense for the three and nine months ended September 30, 2023 and 2022 and the allocation within the condensed consolidated statements of operations and comprehensive loss (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
General and administrative expense	$ 945	$ 1,289	$ 3,014	$ 8,988
Research and development expense	386	(595)	1,120	5,998
Total stock-based compensation	$ 1,331	$ 694	$ 4,134	$ 14,986

Employee Stock Purchase Plan

On April 24, 2019, the Board adopted its 2019 Employee Stock Purchase Plan ("2019 ESPP"), which was subsequently approved by the Company's stockholders and became effective on May 7, 2019, the day immediately prior to the effectiveness of the registration statement filed in connection with the IPO. The 2019 ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Internal Revenue Code (the "Code") for U.S. employees. In addition, the 2019 ESPP authorizes grants of purchase rights that do not comply with Section 423 of the Code under a separate non-423 component for non-U.S. employees and certain non-U.S. service providers. The Company has reserved 1,494,530 shares of common stock for issuance under the 2019 ESPP. In addition, the number of shares reserved for issuance under the 2019 ESPP will be increased automatically on the first day of each fiscal year for a period of up to ten years, starting with the 2020 fiscal year, by a number equal to the least of: (i) 536,589 shares; (ii) 1% of the shares of common stock outstanding on the last day of the prior fiscal year; or (iii) such lesser number of shares determined by the Board. The 2019 ESPP is expected to be implemented through a series of offerings under which participants are granted purchase rights to purchase shares of the Company's common stock on specified dates during such offerings. The Company has not yet approved an offering under the 2019 ESPP.

Rights Plan

On April 5, 2023, the Board declared a dividend of one preferred share purchase right (a "Right") for each outstanding share of the common stock, par value $0.001 per share (the "Common Shares"), of the Company. The dividend is effective as of April 17, 2023 (the "Record Date") with respect to stockholders of record on that date. The Rights will also attach to new Common Shares issued after the Record Date. Each Right entitles the registered holder to purchase from the Company one one-thousandth of a share of Series A Junior Participating Preferred Stock, par value $0.001 per share, (the "Preferred Shares"), of the Company at a price of $6.00 per one one-thousandth of a Preferred Share, subject to adjustment. The descriptions and terms of the Rights are set forth in a Rights Agreement, dated as of April 5, 2023 (the "Rights Agreement"), between the Company and American Stock Transfer & Trust Company, LLC. The Rights will expire on April 5, 2024, unless the Rights are earlier redeemed or exchanged by the Company.

Note 8. Related Party Transactions

David Lamond, Chairperson of the Board was a director and an equity holder in Novosteo, Inc. which Quince acquired on May 19, 2022. The shares of Novosteo, Inc. beneficially owned by Mr. Lamond were automatically canceled and converted into the right to receive shares of Quince common stock in accordance with the terms of the Merger Agreement. The respective boards of directors of Quince and Novosteo have approved the Merger Agreement, and the Novosteo's stockholders adopted the Merger Agreement upon recommendation of the Novosteo board of directors. Mr. Lamond was not part of either company's special committees that evaluated the Novosteo Acquisition and recused himself from board meetings where the Novosteo Acquisition was discussed.

Dirk Thye, M.D., Chief Executive Officer, is an investor in Morphimmune Inc. and Philip Low, Ph.D, a former Board member of Quince Therapeutics, Inc., is a co-founder and Board member of Morphimmune Inc. During the nine months ended September 30, 2023, the Company sold certain lab equipment to Morphimmune Inc. for $80,000 as well as signed a sublease with Morphimmune as the sublessee with total payments of approximately $57,000 for the lease term of March 17, 2023 through December 31, 2023.

On August 4, 2023, the Company entered into a Separation Agreement with Karen Smith, M.D., Ph.D, in which she stepped down as the Chief Medical Officer of the Company, effective as of September 1, 2023. Refer to Note 5 Balance Sheet Components for additional details.

Note 9. Income Taxes

The Company has a history of losses and expects to record a loss in 2023. The Company accounts for income taxes under ASC Topic 740 – *Income Taxes*.

A valuation allowance is provided for significant deferred tax assets when it is more likely than not that such assets will not be realized through future operations. Future tax benefits which may arise as a result of these losses have not been recognized in these financial statements, as their realization is determined not likely to occur and accordingly, the Company has maintained a valuation allowance for the future deferred tax assets.

The Company recorded a discrete tax benefit of $0.2 million in the nine months ended September 30, 2023 due to the release of valuation allowance in connection with the write down of the in-process research and development ("IPR&D") intangible asset related to NOV004. As a result of the impairment, the Company reversed the Deferred tax liabilities associated with the intangible asset resulting in the tax benefit of $0.2 million as of March 31, 2023.

Note 10. Net Loss Per Share

The following outstanding potentially dilutive shares have been excluded from the calculation of diluted net loss per share for the period presented due to their anti-dilutive effect:

	September 30,	
	2023	2022
Stock options issued and outstanding	7,469,163	8,398,987
Restricted stock units	2,975	173,113
Restricted stock awards	200,099	466,750
Total	7,672,237	9,038,850

Note 11. Business Combination

On May 19, 2022, the Company completed the Novosteo Acquisition. Pursuant to the terms of the Merger Agreement, at the closing of the Novosteo Acquisition (the “Effective Time”), each share of capital stock of Novosteo (the “Novosteo Capital Stock”) that was issued and outstanding immediately prior to the Effective Time was automatically cancelled and converted into the right to receive 0.0911 shares of common stock, par value $0.001 per share, of the Company (the “Company Common Stock”). These shares included options to purchase an aggregate of 507,108 shares of the Company Common Stock upon conversion of the outstanding Novosteo options based on the Company Option Exchange Ratio (as defined in the Merger Agreement), with the awards retaining the same vesting and other terms and conditions as in effect immediately prior to consummation of the Novosteo Acquisition. These options, as well as 519,216 unvested restricted shares were concluded to be post-combination expense and were excluded from purchase consideration.

The transaction costs associated with the Novosteo Acquisition were approximately $1.1 million and were recorded in general and administrative expense. The acquisition date fair value of the consideration transferred for Novosteo was approximately $16,502,587, which consisted of 5,000,784 shares at $3.30 per share.

The Company accounted for the Novosteo Acquisition as a business combination in accordance with ASC Topic 805, Business Combinations ("ASC 805"). The Company applied the acquisition method, which requires the identifiable assets acquired and liabilities assumed be recorded at fair value with limited exceptions. The following table summarizes the fair values of the identifiable assets acquired and liabilities assumed as of the date of acquisition (in thousands):

	May 19, 2022
Identifiable assets acquired and liabilities assumed:	
Cash and cash equivalents	$ 10,593
Prepaid expenses and other current assets	1,040
ROU asset	124
Property and equipment	279
Intangible assets	5,900
Accounts payable and accrued liabilities	(1,726)
Deferred tax liabilities	(532)
Net assets acquired	$ 15,678
Goodwill	$ 825

The final determination of the fair value of assets and liabilities was completed within the one-year measurement period as required by ASC 805.

The excess of the fair value of purchase consideration over the fair value of net tangible and identifiable intangible assets acquired was recorded as goodwill, which is primarily attributed to the assembled workforce and expanded market opportunities, for which there is no basis for U.S. income tax purposes. Goodwill amounts are not amortized but are rather tested for impairment at least annually, see Note 12 for this assessment. Goodwill is not deductible for tax purposes.

The Intangible asset balance above is attributable to in-process research and development with an indefinite useful life.

The amounts of Novosteo's net loss was $2.7 million and $5.2 million, respectively, included in the Company's condensed consolidated statement of operations and comprehensive loss for the three and nine months ended September 30, 2022. The amount of Novosteo's revenue was $0 for both the three and nine months ended September 30, 2022. The unaudited pro forma revenue and net loss of the combined entity had the acquisition date been January 1, 2022 are as follows:

	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2022
Revenue	$ —	$ 262
Net loss	(7,921)	(47,057)

Note 12. Intangible Assets

The intangible asset acquired as a result of the Novosteo Acquisition consists of in-process research and development ("IPR&D") related to NOV004, the Company's bone targeting molecule designed to accelerate fracture repair. The value of the IPR&D was determined using discounted probable future cash flows.

Significant assumptions used in determining the value of the intellectual property include the initiation of clinical trials and NDA approval with respect to NOV004, probability of reaching various phases of development, costs and cost of goods sold, and the risk adjusted discount rate applied to the cash flows.

All intangible assets acquired in a business combination that are used in research and development activities are capitalized as indefinite-lived intangible assets. During the period that those assets are considered indefinite lived, they are not amortized but are tested for impairment. Once the research and development efforts are completed, the asset will be amortized over its remaining useful life. If the research and development efforts are abandoned, the intangible asset will be expensed in that period.

The following table provides details of the carrying amount of our indefinite-lived intangible asset (in thousands):

	As of September 30, 2023
Unamortized intangible assets:	
In-process research and development	$ 5,900
Impairment charge	(5,900)
Balance as of September 30, 2023	—

In January 2023, the Company decided to discontinue the internal development of NOV004 and pursue out-licensing opportunities. As a result, several of the assumptions used in determining the initial fair value have changed including discount rate and expected cash flows and thus triggered the need for an interim impairment assessment as required under ASC 350. And so, the Company performed a fair value assessment of the Intellectual Property as of March 31, 2023, and based upon this assessment, the fair value was determined to be significantly below its carrying value and resulted in an asset impairment charge of $5.9 million during the three months ended March 31, 2023.

Goodwill

The excess of the fair value of purchase consideration over the fair value of net tangible and identifiable intangible assets acquired was recorded as goodwill.

There was no amount related to goodwill reflected on the condensed consolidated balance sheet for the Company as of September 30, 2023 and December 31, 2022. In 2022, management performed an impairment evaluation of goodwill after assessing qualitative factors that indicated a possible impairment of goodwill. Under the qualitative assessment, management considers relevant events and circumstances including but not limited to macroeconomic conditions, industry and market considerations, overall Company performance and events directly affecting the Company. It was noted during our assessment that the Company's market capitalization was significantly below its carrying value and a further quantitative analysis was conducted to determine to the extent, if any, the Company's carrying value exceeded its fair value as of September 30, 2022. The quantitative analysis used fair value based on market capitalization adjusted for control premium based on market comparable transactions. This quantitative analysis resulted in the Company's fair value being significantly below its carrying value, resulting in a non-cash goodwill impairment charge of $0.8 million being recorded during the year ended December 31, 2022.

Note 13. Subsequent Events

On October 20, 2023, the Company completed its acquisition of EryDel S.p.A., a privately-held, late-stage biotechnology company with a lead Phase 3 lead asset, EryDex, that targets the treatment of a rare neurodegenerative disease, Ataxia-Telangiectasia, for which there are currently no approved treatments globally. The Company will account for this acquisition in accordance with ASC 805, Business Combinations, which requires the assets acquired and the liabilities assumed to be measured at fair value at the date of the acquisition. The accounting for the acquisition is incomplete as of the date of this Quarterly Report on Form 10-Q.

The EryDel Acquisition was pursuant to that certain Stock Purchase Agreement, dated as of July 21, 2023, by and among the Company, EryDel, EryDel Italy, Inc., holders of EryDel capital stock and the managers of EryDel and Shareholder Representative Services LLC, a Colorado limited liability company solely in its capacity as the representative, agent and attorney-in-fact of the EryDel Shareholders. Pursuant to the terms of the Purchase Agreement, the Company issued 6,525,315 shares of common stock of the Company, approximately equivalent to $6.5 million, to the EryDel Shareholders, resulting in the EryDel Shareholders owning approximately 15.2% of the outstanding common stock of the Company. Up to an additional 725,037 shares of the Company’s common stock may be issued to the EryDel Shareholders upon the first anniversary of the closing of the EryDel Acquisition. The EryDel Shareholders have a contingent right to receive up to an aggregate of $485,000,000 in potential cash payments, comprised of up to $5,000,000 upon the achievement of a specified development milestone, $25,000,000 at NDA acceptance by the FDA, up to $60,000,000 upon the achievement of specified approval milestones, and up to $395,000,000 upon the achievement of specified on market and sales milestones, with no royalties paid to EryDel.

In connection with the closing of the EryDel Acquisition, Quince, together with its wholly owned subsidiaries, EryDel Italy, Inc., a Delaware corporation, and EryDel US, Inc., a Delaware corporation (each a “Quince Party” and together, collectively, the “Quince Parties”), have agreed to guarantee the obligations of EryDel, a company with shares incorporated under the laws of Italy, in respect of a $31.8 million unsecured credit facility (the “EIB Facility”) evidenced by the Finance Contract, dated as of July 24, 2020 (the “Existing Finance Contract” and, as amended by the Amendment, the “Amended Finance Contract”), by and between EryDel, as borrower, and the European Investment Bank, as lender (the “Lender”), by entering into (i) an Accession, Amendment and Restatement Agreement, dated as of October 20, 2023 (the “Amendment”), which amends and restates the Existing Finance Contract and joins each Quince Party thereto as a guarantor of the obligations of EryDel thereunder, and (ii) an Autonomous First Demand Guarantee (Garanzia Autonoma a Prima Richiesta) by each Quince Party respectively in favor of the Lender (collectively, the “Guarantees”).

As of October 20, 2023, approximately $10.6 million has been disbursed to EryDel. The outstanding principal amount under the EIB Facility will become due and payable at maturity on August 11, 2026 and bears interest at a fixed rate of 9.00% per annum. The EIB Facility may be voluntarily prepaid at any time with at least 60 days' prior notice, subject to a prepayment penalty.

Pursuant to the EIB Facility, each Quince Party will (i) make representations and warranties to EIB that are customary for facilities similar to the EIB Facility and (ii) become bound by customary affirmative and negative covenants, subject to customary exceptions. Quince, but not the other Quince Parties, will become subject to a requirement under the EIB Facility to maintain a certain minimum unrestricted balance of cash or cash equivalents during the term of the EIB Facility. A failure by a Quince Party to comply with any of the covenants applicable to it under the EIB Facility will, either immediately or after the passage of time in the case of those covenants that are subject to a grace period, constitute an event of default under the EIB Facility. Pursuant to the Guarantees, each Quince Party has agreed to guarantee EryDel's obligations under the EIB Facility, which must be paid to EIB within five (5) business days of written demand therefor from EIB.

Under the Promissory Note entered into on August 30, 2023, discussed in Note 5 Balance Sheet Components, EryDel Italy, Inc. provided the second tranche on October 17, 2023 in an amount of $500,000 with 5.22% annual interest to EryDel. On October 24, 2023, in connection with the EryDel Acquisition, the outstanding principal and accrued interest due under the Promissory Note of approximately $1.0 million in the aggregate was deemed to be paid and discharged in full.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with (i) our unaudited condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and (ii) our audited financial statements and related notes and management's discussion and analysis of financial condition and results of operations included in our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the Securities and Exchange Commission (the "SEC"), on March 15, 2023. Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to the "Company," "Quince," "we," "us" and "our" refer to Quince Therapeutics, Inc. and "our legacy assets" refer to atuzaginstat (COR388), COR588, COR852, and COR803, collectively.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts contained in this quarterly report, including statements regarding our ability to achieve the anticipated benefits of the EryDel Acquisition, anticipated clinical and development activities related to EryDex, a potential NDA submission to the FDA, the timing and success of the Company's clinical trials, including a single Phase 3 NEAT (Neurologic Effects of EryDex on Subjects with A-T) clinical trial ("Phase 3 NEAT trial"), our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, timing and likelihood of success, plans and objectives of management for future operations, adequacy of our cash resources and working capital, and potential acquisitions on in-licensing of new products, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this quarterly report are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in this Quarterly Report in Part II, Item 1A -"Risk Factors," and in our Annual Report on Form 10-K for the year ended December 31, 2022 and elsewhere in this Quarterly Report on Form 10-Q and in other filings we make with the SEC from time to time. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. These forward-looking statements speak only as of the date hereof. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Overview

Following our acquisition of EryDel in October 2023, we shifted our strategic focus to become a late-stage biotechnology company dedicated to unlocking the power of a patient's own biology to deliver innovative and life-changing therapeutics to those living with rare diseases. Our lead asset, EryDex, which is being developed for the treatment of a rare neurodegenerative disease, Ataxia-Telangiectasia (A-T), is expected to begin a pivotal Phase 3 NEAT trial in the second quarter of 2024. Currently, there are no approved treatments for A-T. EryDex utilizes a highly differentiated technology platform for autologous intracellular drug encapsulation (AIDE). Our proprietary AIDE technology is designed to optimize the biodistribution and pharmacokinetics of dexamethasone sodium phosphate (DSP; a pro-drug) by using an A-T patient's own red blood cells to deliver the sustained therapeutic once monthly over a treatment period. It is also designed to allow for the chronic administration of the therapeutic. Our flexible and expandable AIDE technology platform is designed to deliver a variety of therapeutics, ranging from small to large molecules, as well as biologics. We intend to investigate additional potential applications of the AIDE technology platform in different indications in the future.

Our predecessor company, Cortexyme, Inc. ("Cortexyme") was initially founded on the seminal discovery of the presence of P. gingivalis and its secreted toxic virulence factor proteases, called gingipains, in the relevant brain areas of both Alzheimer's and Parkinson's disease patients. Following our acquisition of Novosteo, Inc. in May 2022 and the addition of new executive management, we strategically shifted focus and prioritized the internal development of Novosteo's innovative bone-targeting drug platform and lead preclinical compound NOV004 for development for rare skeletal diseases, bone fractures, and injury. Shortly thereafter, we changed our corporate name to Quince Therapeutics, Inc. in August 2022. At that time, we also announced our intention to actively seek

compelling clinical-stage assets available for in-licensing and acquisition to expand our development pipeline with a focus on acquiring, developing, and commercializing innovative therapeutics for patients suffering from debilitating and rare diseases.

Business Update

On October 20, 2023, we completed our previously announced acquisition (the "EryDel Acquisition") of EryDel, pursuant to that certain Stock Purchase Agreement, dated as of July 21, 2023, (the "Purchase Agreement"), by and among us, EryDel, EryDel Italy, Inc., holders of EryDel capital stock and the managers of EryDel (the "EryDel Shareholders") and Shareholder Representative Services LLC, a Colorado limited liability company solely in its capacity as the representative, agent and attorney-in-fact of the EryDel Shareholders. Pursuant to the terms of the Purchase Agreement, we issued 6,525,315 shares of our common stock to the EryDel Shareholders, resulting in the EryDel Shareholders owning approximately 15.2% of the outstanding common stock of the Company. Up to an additional 725,037 shares of the Company's common stock may be issued to the EryDel Shareholders upon the first anniversary of the closing of the EryDel Acquisition. The EryDel Shareholders have a contingent right to receive up to an aggregate of $485,000,000 in potential cash payments, comprised of up to $5,000,000 upon the achievement of a specified development milestone, $25,000,000 at NDA acceptance by the FDA, up to $60,000,000 upon the achievement of specified approval milestones, and up to $395,000,000 upon the achievement of specified on market and sales milestones, with no royalties paid to EryDel.

Sale of Legacy Portfolio

On January 27, 2023, we sold our legacy small molecule protease inhibitor portfolio, including COR588, COR388, COR852, and COR803, pursuant to an asset purchase agreement with Lighthouse Pharmaceuticals, Inc., (the "Purchaser" or "Lighthouse") an entity co-founded by Casey Lynch, former chief executive officer of Cortexyme.

Upon the consummation of the transaction, we received shares of common stock of Purchaser ("Common Stock") equal to seven and a half percent (7.5%) of the currently issued and outstanding Common Stock. The issuance is governed by a Stock Issuance Agreement entered into by us and the Purchaser on January 27, 2023 (the "Stock Agreement").

Pursuant to the terms of the asset purchase agreement, we are eligible to receive milestone payments up to $150 million on a product by product basis for the achievement of certain regulatory approvals and global net sales thresholds. Additionally, we are eligible to receive certain sales-based royalty payments on a product by product basis, ranging from high single-digit to mid-teens of annual net sales related to the two existing clinical stage programs, and low single-digit royalties for the preclinical programs, and certain sublicense income on a product by product basis, either in addition to milestone payments and royalties prior to Phase 2 initiation for COR588 or COR388, or in lieu of milestones payments and royalties after initiation of Phase 2 for COR588 or COR388 or for the preclinical programs.

Rights Plan

On April 5, 2023, the Board declared a dividend of one preferred share purchase right (a "Right") for each outstanding share of the common stock, par value $0.001 per share (the "Common Shares"), of the Company. The dividend is effective as of April 17, 2023 (the "Record Date") with respect to stockholders of record on that date. The Rights will also attach to new Common Shares issued after the Record Date. Each Right entitles the registered holder to purchase from the Company one one-thousandth of a share of Series A Junior Participating Preferred Stock, par value $0.001 per share, (the "Preferred Shares"), of the Company at a price of $6.00 per one one-thousandth of a Preferred Share, subject to adjustment. The descriptions and terms of the Rights are set forth in a Rights Agreement, dated as of April 5, 2023 (the "Rights Agreement"), between the Company and American Stock Transfer & Trust Company, LLC. The Rights will expire on April 5, 2024, unless the Rights are earlier redeemed or exchanged by the Company.

Corporate Restructuring

In January 2023, we approved a cost reduction program (the "Plan") to align operations with changes in our corporate strategy. Under the Plan, we reduced headcount by approximately 47% through a reduction in our workforce. The reduction in force began in February 2023 and was completed in April 2023.

In connection with the Plan, we incurred expenses of approximately $0.4 million, substantially all of which were cash expenditures relating to severance through April 2023.

Financial Overview

Following our acquisition of EryDel in October 2023, we shifted our strategic focus to become a late-stage biotechnology company dedicated to unlocking the power of a patient's own biology to deliver innovative and life-changing therapeutics to those living with rare diseases. We intend to focus our development expertise and financial resources toward advancing a single Phase 3 NEAT trial, which is a multicenter, randomized, double-blind, placebo-controlled study to evaluate the neurological effects of EryDex on patients with A-T. Enrollment for the Phase 3 NEAT trial is expected to begin in the second quarter of 2024. We plan to enroll approximately 86 A-T patients aged six to nine years-old and approximately 20 additional A-T patients aged 10 years or older. This pivotal clinical trial will be conducted under a Special Protocol Assessment (SPA) that has been agreed with the U.S. Food & Drug Administration (FDA), which should allow for the submission of a New Drug Application (NDA) following completion of this single study, assuming positive results. With $83.2 million of cash, cash equivalents and short-term investments as of September 30, 2023, we believe we are well-capitalized into 2026 with ability to fully fund our lead asset, EryDex, expected through Phase 3 clinical trial under SPA and to NDA submission, assuming positive study results, excluding any costs or cash expenditures associated with any additional potential asset acquisitions.

Previously, we had devoted substantially all of our efforts and financial resources to building our research and development capabilities, establishing our corporate infrastructure, and most recently, readying our bone targeting drug NOV004 for Phase 1 clinical trials, and prior to that, since commencing material operations in 2014, executing our Phase1a, Phase 1b and Phase 2/3 clinical trials of our legacy small molecule protease inhibitor portfolio, including atuzaginstat (COR388), our Phase I SAD/MAD clinical trial of COR588. We have sold our legacy small molecule protease inhibitor portfolio and intend to out-license our NOV004 bone targeting drug.

To date, we have not generated any product revenue and we have never been profitable. We have incurred net losses since the commencement of our operations. As of September 30, 2023, we had an accumulated deficit of $310.8 million. We incurred a net loss of $5.4 million and $22.5 million in the three and nine months ended September 30, 2023. We do not expect to generate product revenue unless and until we obtain marketing approval for and commercialize a drug candidate, and we cannot assure you that we will ever generate significant revenue or profits.

To date, we have financed our operations primarily through the issuance and sale of convertible promissory notes and redeemable convertible preferred stock and common stock. From inception through September 30, 2023, we received net proceeds of approximately $303.8 million from the issuance of redeemable convertible preferred stock, convertible promissory notes and common stock.

On December 23, 2021, we entered into an Open Market Sales Agreement, with Jefferies LLC (the "Sales Agreement"). We did not sell any shares or receive any proceeds during the three and nine months ended September 30, 2023. During the three and nine months ended September 30, 2022, we sold zero and 51,769 shares of common stock, respectively, under the Sales Agreement and received net proceeds of $0 and $0.6 million, respectively. The registration statement registering the shares subject to the Sales Agreement has expired as of June 1, 2023.

As of September 30, 2023 and December 31, 2022, we had cash, cash equivalents and short-term investments of $83.2 million and $90.2 million, respectively. The balances exclude long-term investments of $0 and $3.6 million as of those same periods. Our cash equivalents and short-term investments are held in money market funds, certificate of deposits, repurchase agreements, investments in corporate debt securities, municipal debt obligations and government agency obligations.

We believe that our existing cash, cash equivalents and investments will be sufficient to fund our planned operations, which include the anticipated clinical and development activities related to our recently acquired lead asset, EryDex, through a single Phase 3 NEAT trial, and a potential NDA submission to the FDA, assuming positive results, into at least 2026, but does not include any costs or cash expenditures associated with any additional potential asset acquisitions. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

In response to the reprioritization of our pipeline on January 30, 2023, the Board approved a cost reduction program to align operations with the change in corporate strategy to prioritize capital resources toward the expansion of its development pipeline through opportunistic in-licensing and acquisition of clinical-stage assets targeting debilitating and rare diseases. Under the Plan, we reduced headcount by approximately 47% through a reduction in our workforce. The reduction in force began in February 2023 was completed in April 2023.

We will need substantial additional funding to support our continuing operations and pursue our development strategy. Until such time as we can generate significant revenue from sales of an approved drug, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources. Adequate funding may not be available to us on acceptable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of our drug candidates or delay our efforts to expand our product pipeline.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe that the assumptions and estimates associated with accrued research and development expenditures, stock-based compensation, and assumptions regarding intangible valuation resulting from the Novosteo Acquisition have the most significant impact on our condensed consolidated financial statements. Therefore, we consider these to be our critical accounting policies and estimates.

The following critical accounting policies are described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies, Significant Judgements and Use Estimates" in our 2022 Annual Report on Form 10-K and the notes to the unaudited condensed consolidated financial statements included in Part I, Item 1, "Unaudited Financial Statements," of this Quarterly Report on Form 10-Q. We believe that of our critical accounting policies, the following accounting policies are the most critical to fully understanding and evaluating our financial condition and results of operations:

- Research and Development Expenses
- Stock-based Compensation Expenses
- Income Taxes
- Business Combination
- Goodwill
- Identifiable Intangible Assets

There have been no material changes in our critical accounting policies during the nine months ended September 30, 2023, as compared to those disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies, Significant Judgments and Use of Estimates" in our Annual Report on Form 10-K.

Components of Results of Operations

Operating Expenses

Research and Development Expenses

Our research and development expenses consist of expenses incurred in connection with the research and development of our research programs. These expenses include payroll and personnel expenses, including stock-based compensation, for our research and product development employees, laboratory supplies, product licenses, consulting costs, contract research, manufacturing, regulatory, quality assurance, preclinical and clinical expenses, allocated rent, facilities costs and depreciation. We expense both internal and external research and development costs as they are incurred. Non-refundable advance payments and deposits for services that will be used or rendered for future research and development activities are recorded as prepaid expenses and recognized as an expense as the related services are performed.

To date, our research and development expenses have supported the advancement of atuzaginstat (COR388) and COR588 and to a lesser extent the clinical and regulatory development of NOV004. We expect our research and development expenses to increase significantly from current levels as we begin the Phase 3 NEAT trial.

In addition, the probability of success of any additional in-licensed product candidate will depend on numerous factors, including safety, efficacy, competition, manufacturing capability and commercial viability. We will need to determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, as well as an assessment of each product candidate's commercial potential.

We cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidate or whether, or when, we may achieve profitability.

General and Administrative

General and administrative expenses consist principally of personnel-related costs, including payroll and stock-based compensation, for personnel in executive, finance, human resources, business and corporate development, and other administrative functions, professional fees for legal, consulting, insurance and accounting services, allocated rent and other facilities costs, depreciation, and other general operating expenses not otherwise classified as research and development expenses.

We anticipate that our general and administrative expenses will increase as a result of the EryDel Acquisition. We anticipate an increase of our general and administrative expense after the EryDel Acquisition as the size of our business and research and development operations would need to grow to support additional research and development activities.

Interest Income

Interest and other income, net consists primarily of interest earned on our short-term and long-term investments portfolio.

Results of Operations

Comparison of the three months ended September 30, 2023 to the three months ended September 30, 2022

The following sets forth our results of operations for the three months ended September 30, 2023 and 2022 (in thousands):

	Three Months Ended September 30,		Change	
	2023	2022	$	%
Operating expenses:				
Research and development	$ 1,431	$ 2,451	$ (1,020)	(41.6) %
General and administrative	4,663	4,344	319	7.3 %
Goodwill impairment charge	—	825	(825)	(100.0) %
Loss from operations	(6,094)	(7,620)	1,526	(20.0) %
Interest income	959	315	644	204.4 %
Other expense, net	(216)	(616)	400	(64.9) %
Net loss before income tax benefit	$ (5,351)	$ (7,921)	2,570	(32.4) %
Income tax benefit	—	—	—	— %
Net loss	$ (5,351)	$ (7,921)	$ 2,570	(32.4) %

Research and Development Expenses *(in thousands):*

	Three Months Ended September 30,		Change	
	2023	2022	$	%
Direct research and development expenses:				
Atuzaginstat (COR388)	$ —	$ 107	$ (107)	(100.0) %
COR588	17	841	(824)	(98.0) %
NOV004	—	763	(763)	(100.0) %
Other direct research costs	—	82	(82)	(100.0) %
Indirect research and development expenses:				
Personnel related (including stock-based compensation)	1,311	566	745	131.6 %
Facilities and other research and development expenses	103	92	11	12.0 %
Total research and development expenses	$ 1,431	$ 2,451	$ (1,020)	(41.6) %

Research and development expenses were $1.4 million for the three months ended September 30, 2023, compared to $2.4 million for the three months ended September 30, 2022, a decrease of $1.0 million.

The costs for atuzaginstat (COR388) decreased by $0.1 million in the three months ended September 30, 2023 as compared to the prior year period due to conclusion of GAIN trial in the fourth quarter of 2021 and minimal related costs being incurred in the third quarter of 2023 as compared to the third quarter of 2022.

Our Phase 1 SAD/MAD testing in healthy volunteers was completed in the second quarter of 2022. As a result, the costs for COR588 decreased $0.8 million in the three months ended September 30, 2023 as compared to the prior year period due to $0.5 million decrease for non-clinical work supporting COR588, a $0.2 million decrease in drug manufacturing costs, as well as a $0.1 million decrease in clinical trial costs.

In the quarter ended September 30, 2023, the costs for NOV004 decreased by $0.8 million as compared to the prior year period primarily due to the decision made on January 30, 2023 to discontinue development of NOV004 to align with our updated corporate strategy. There was a $0.4 million decrease in drug manufacturing costs, a $0.2 million decrease in consulting and legal costs related to NOV004, as well as a $0.1 million decrease for non-clinical work supporting NOV004.

In the quarter ended September 30, 2023, other direct research costs decreased $0.1 million primarily due to the winddown of pipeline development of our two arginine gingipain inhibitors, COR788 and COR822, our 3CLpro inhibitor, COR803, COR852 and other preclinical research related to our legacy assets which were sold to Lighthouse in January 2023.

We also incurred increases of $0.7 million in personnel related expenses in the three months ended September 30, 2023 due to a $1.0 million increase in allocated stock-based compensation costs, an increase of $0.5 million of severance incurred, offset by a decrease of $0.8 million related to reduced headcount year over year.

Facilities and other research and development expenses remained generally consistent for the three months ended September 30, 2023, as compared to the three months ended September 30, 2022.

General and Administrative Expenses

General and administrative expenses increased by $0.3 million to $4.7 million for the three months ended September 30, 2023 from $4.3 million for the three months ended September 30, 2022. The increase in general and administrative expenses is primarily due to an increase of $0.7 million in consulting expenses related to business development expenses and a $0.5 million increase in legal and other professional fees to support the EryDel transaction. The increase is partially offset by a $0.5 million decrease in corporate insurance expenses due to lower Director & Officers insurance premiums, as well as lower audit and tax expense. The increase is also partially offset by a decrease of $0.4 million in personnel related expenses due to a $0.3 million decrease in allocated stock-based compensation expense, and a decrease of $0.1 million related to reduced headcount year over year.

Goodwill Impairment Charge

As of September 30, 2022, we conducted an impairment analysis of our goodwill that resulted from the purchase of Novosteo, Inc. in May 2022. That assessment included a qualitative assessment of deteriorating macro-economic conditions, including inflationary pressures, rising interest rates, and the continuing decline in our market capitalization from the date of acquisition. This qualitative assessment indicated that our goodwill was potentially impaired. To determine the extent, if any, by which our goodwill was impaired, we conducted additional quantitative analyses which resulted in our fair value being significantly below our current carrying value. As a result of the analyses, we recorded a non-cash goodwill impairment charge of $0.8 million for the three months ended September 30, 2022. There have been no additional impairment charges since the prior period as no goodwill remained on the books.

Interest Income

Interest income increased by $0.6 million for the three months ended September 30, 2023, as compared to the three months ended September 30, 2022. The increase was due to increased yields on our investment portfolio which were partially offset by decreased average balances.

Other Expense

Other expense decreased by $0.4 million for the three months ended September 30, 2023, primarily due to unrealized losses resulting from changes in foreign exchange rates.

Comparison of the nine months ended September 30, 2023 to the nine months ended September 30, 2022

The following sets forth our results of operations for the nine months ended September 30, 2023 and 2022 (in thousands):

	Nine Months Ended September 30,		Change	
	2023	2022	$	%
Operating expenses:				
Research and development	$ 6,013	$ 22,410	$ (16,397)	(73.2) %
General and administrative	12,786	22,461	(9,675)	(43.1) %
Goodwill impairment charge	—	825	(825)	(100.0) %
Intangible asset impairment charge	5,900	—	5,900	100.0 %
Loss from operations	(24,699)	(45,696)	20,997	(45.9) %
Interest income	2,464	532	1,932	363.2 %
Other expense, net	(504)	(1,246)	742	(59.6) %
Net loss before income tax benefit	$ (22,739)	$ (46,410)	$ 23,671	(51.0) %
Income tax benefit	248	284	(36)	(12.7) %
Net loss	$ (22,491)	$ (46,126)	$ 23,635	(51.2) %

Research and Development Expenses *(in thousands):*

	Nine Months Ended September 30,		Change	
	2023	2022	$	%
Direct research and development expenses:				
Atuzaginstat (COR388)	$ 153	$ 1,368	$ (1,215)	(88.8) %
COR588	28	4,851	(4,823)	(99.4) %
NOV004	2,013	1,082	931	86.0 %
Other direct research costs	28	1,489	(1,461)	(98.1) %
Indirect research and development expenses:				
Personnel related (including stock-based compensation)	3,405	12,903	(9,498)	(73.6) %
Facilities and other research and development expenses	386	717	(331)	(46.2) %
Total research and development expenses	$ 6,013	$ 22,410	$ (16,397)	(73.2) %

Research and development expenses were $6.0 million for the nine months ended September 30, 2023, compared to $22.4 million for the nine months ended September 30, 2022, a decrease of $16.4 million.

The costs for atuzaginstat (COR388) development decreased $1.2 million from the same period in the prior year due to a decrease of $0.8 million in drug manufacturing costs and a decrease of $0.4 million related to consulting for atuzaginstat (COR388).

Our Phase 1 SAD/MAD testing in healthy volunteers was completed in the second quarter of 2022. As a result, the costs for COR588 decreased $4.8 million from the same period in the prior year due to a decrease of $2.5 million for non-clinical studies to support COR588, a $1.5 million decrease in drug manufacturing costs, a $0.7 million decrease in clinical trial costs, and a $0.1 million decrease in consulting expenses to support COR588.

As we sold our legacy protease inhibitor portfolio including COR388 and COR588 to Lighthouse in January 2023, we do not expect any additional expenses related to these legacy assets from the second quarter of 2023 onward.

For the nine months ended September 30, 2023, the costs for NOV004 increased by $0.9 million after the Novosteo Acquisition on May 19, 2022, primarily as a result of the increase in drug manufacturing costs as we prepared our compound for Phase 1 clinical trials. Due to the decision made on January 30, 2023 to align with our updated corporate strategy, our NOV004 costs will be minimal for the remainder of 2023.

Additionally, for the nine months ended September 30, 2023, other direct research costs decreased $1.5 million primarily due to the winddown of pipeline development of our two arginine gingipain inhibitors, COR788 and COR822, our 3CLpro inhibitor, COR803, COR852 and other preclinical research related to our legacy assets which were sold to Lighthouse in January 2023.

For the nine months ended September 30, 2023, we also experienced a net decrease of $9.5 million in personnel related expenses as a result of a $4.9 million decrease in allocated stock-based compensation costs, a decrease of $1.6 million of severance incurred, and a decrease of $3.0 million related to reduced headcount year over year.

For the nine months ended September 30, 2023, facilities and other research and development expenses decreased $0.3 million from the nine months ended September 30, 2022 primarily due to a $0.2 million decrease in rent and facilities expenses related to the termination of the Purdue lease and a decrease in storage fees for samples and a $0.1 million decrease in the purchase of non-clinical supplies

General and Administrative Expenses

General and administrative expenses decreased approximately $9.7 million to $12.8 million for the nine months ended September 30, 2023 from $22.5 million for the nine months ended September 30, 2022. The decrease in general and administrative expenses is primarily due to a decrease of $8.5 million in personnel related expenses due to a $6.0 million decrease in allocated stock-based compensation expense, a $1.6 million decrease of severance incurred, and a decrease of $0.9 million related to reduced headcount year over year. We also incurred a $0.6 million decrease in legal fees and a $1.6 million decrease in corporate insurance expenses, facilities, and other administrative expense due to our cost reductions efforts announced in the first quarter of 2023 and lower Director & Officers insurance premiums. This was partially offset by an increase of $1.0 million in business development consulting related to the EryDel transaction and a $0.1 million increase in audit and tax fees quarter over quarter.

Intangible Asset Impairment Charge

As of March 31, 2023, we conducted an impairment analysis of our intangible asset IPR&D that resulted from the purchase of Novosteo, Inc. in May 2022. To determine the extent, if any, by which our IPR&D Intangible Asset was impaired, we conducted a quantitative analysis which resulted in our fair value being significantly below our current carrying value due to the assumptions changing as a result of the decision to hold this asset for sale in January 2023. As a result of the analyses, we recorded a non-cash intangible asset IPR&D impairment charge of $5.9 million for the nine months ended September 30, 2023.

Interest Income

Interest income was $2.5 million for the nine months ended September 30, 2023 compared to $0.5 million for the nine months ended September 30, 2022. The increase was due to increased yields on our investment portfolio which were partially offset by decreased average balances.

Other Expense

Other expense decreased by $0.7 million for the nine months ended September 30, 2023, primarily due to $0.5 million lower of unrealized losses resulting from changes in foreign exchange rates, as well as a $0.2 million decrease related to the San Diego lease impairment loss and loss on disposal of fixed assets incurred during the nine months ended September 30, 2022.

Income Tax

There was no change in the income tax benefit as we recorded an $0.2 million income tax benefit for the nine months ended September 30, 2023 as a result of the quantitative and qualitative analysis that concluded in the NOV004 asset being fully impaired and written off.

Liquidity, Capital Resources and Plan of Operations

We have incurred cumulative net losses and negative cash flows from operations since our inception and anticipate we will continue to incur net losses for the foreseeable future. As of September 30, 2023, we had an accumulated deficit of $310.8 million. and we had cash, cash equivalents and investments of $83.2 million.

Based on our existing business plan, we believe that our existing cash, cash equivalents and investments will be sufficient to fund our planned operations, which would include anticipated clinical and development activities related to EryDel's lead asset through potential NDA submission to the FDA, assuming positive results from the Phase 3 NEAT trial, into at least 2026, but does not include any costs or cash expenditures associated with any additional potential asset acquisition.

Capital Resources

Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures related to NOV004, business development expenses, and other general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

In January 2023 we out-licensed our legacy protease inhibitors to Lighthouse and announced our intention to out-license our current preclinical drug candidate NOV004. We also intend to concentrate our efforts on in-licensing clinical-stage assets targeting debilitating and rare diseases. Accordingly, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of any potential future product candidates or whether, or when, we may achieve profitability.

In the near term, our primary uses of cash will be to fund our operations, including business development activities, and administrative personnel related expenses. Our uses of cash beyond the next 12 months will depend on many factors, including integration of EryDel assets and initiation of Phase 3 NEAT trial, and the general economic environment in which we operate and our ability to progress on our additional out-licensing and in-licensing timelines, which are uncertain.

We may continue to require additional capital to develop our drug candidates and fund operations for the foreseeable future. We may seek to raise capital through private or public equity or debt financings, collaborative or other arrangements with other companies, or through other sources of financing. Adequate additional funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. We anticipate that we will need to raise substantial additional capital, the requirements of which will depend on many factors, including:

- the progress, costs, trial design, results of and timing of any potential future trials;
- the outcome, costs and timing of seeking and obtaining FDA and any other regulatory approvals;
- the number and characteristics of drug candidates that we pursue;
- our need to expand our research and development activities in connection with any assets that we have acquired or may in-license;
- the costs of acquiring, licensing or investing in businesses, drug candidates and technologies;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to retain management and hire scientific and clinical personnel;
- the effect of competing drugs and drug candidates and other market developments;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and
- the economic and other terms, timing of and success of any collaboration, licensing or other arrangements into which we may enter in the future.

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain

merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials. We may also be required to sell or license to other rights to our drug candidates in certain territories or indications that we would prefer to develop and commercialize ourselves.

Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide. However, based on our current business plans, we believe that our existing cash, cash equivalents and investments will be sufficient to fund our planned operations, which would include anticipated clinical and development activities related to EryDel's lead asset through potential NDA submission to the FDA, assuming positive results from the Phase 3 NEAT trial, through at least 2026, but does not include any costs or cash expenditures associated with any additional potential asset acquisition.

Summary Statement of Cash Flows

Cash Flows

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented below (in thousands):

	Nine Months Ended September 30,	
	2023	**2022**
Net cash (used in) provided by:		
Operating activities	$ (12,214)	$ (38,203)
Investing activities	(11,148)	(664)
Financing activities	86	725
Effect of exchange rate changes on cash	329	227
Net decrease in cash and cash equivalents	$ (22,947)	$ (37,915)

Operating Activities

Net cash used in operating activities was $12.2 million for the nine months ended September 30, 2023. Cash used in operating activities was primarily due to our net loss of $22.5 million for the period, adjusted for $8.6 million of non-cash items, including $4.1 million in stock-based compensation and $5.9 million in impairment loss due to the write down of the IPR&D asset, as well as a net increase in our current assets of $2.4 million, offset by a net decrease in accounts payable, accrued expenses and other current liabilities of $0.7 million.

Net cash used in operating activities was $38.2 million for the nine months ended September 30, 2022. Cash used in operating activities was primarily due to our net loss of $46.1 million for the period, adjusted for $16.0 million of non-cash items, including $15.0 million in stock-based compensation and a net decrease in our current assets of $2.6 million, offset by a net decrease in accounts payable, accrued expenses and other current liabilities of $10.6 million.

Investing Activities

Net cash used by investing activities was $11.1 million in the nine months ended September 30, 2023, primarily related to the purchase of investments of $95.1 million, and maturities of investments of $84.5 million.

Net cash provided by investing activities was $0.7 million in the nine months ended September 30, 2022, primarily related to the purchase of investments of $66.8 million, maturities of investments of $55.5 million, cash acquired from the Novosteo Acquisition of $10.6 million.

Financing Activities

Net cash provided by financing activities was $0.1 million in the nine months ended September 30, 2023, which consisted of net proceeds from the exercise of stock options in the period.

Net cash provided by financing activities was $0.7 million in the nine months ended September 30, 2022, which consisted of proceeds from the issuance of common stock in connection with an open market sales agreement, net of issuance costs as well as proceeds from the exercise of options.

Contractual Obligations and Commitments

Except as discussed below, there have been no material changes to our contractual obligations and other commitments as of September 30, 2023, as compared to those disclosed in our Annual Report on Form 10-K.

Our contractual obligations primarily consist of our obligations under non-cancellable operating leases and other purchase obligations.

We enter into contracts in the normal course of business with third party contract organizations for clinical trials, non-clinical studies and testing, manufacturing, and other services and products for operating purposes. The amount and timing of the payments under these contracts varies based upon the timing of the services. We have recorded accrued expense of approximately $0.4 million in our condensed consolidated balance sheet for expenditures incurred by these vendors as of September 30, 2023. Other than our operating lease commitments, we do not have any material non-cancellable future commitments based on existing contracts as of September 30, 2023. Refer to Note 13 Subsequent Events for other contractual obligations and commitments related to the EryDel Acquisition and for the new lease refer to Note 6 Leases.

Recent Accounting Pronouncements

Please refer to Note 2 to our unaudited condensed consolidated financial statements appearing under Part 1, Item 1 of this report for a discussion of new accounting standards updates that may impact us.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and are not required to provide the information required under this item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our disclosure controls and procedures are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act, is recorded, communicated to our management to allow timely decisions regarding required disclosure, summarized and reported within the time periods specified in the SEC's rules and forms. Any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Under the supervision and with the participation of our management, including the Chief Executive Officer and Principal Financial Officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures, as such term is defined under Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of September 30, 2023. Based on that evaluation, the Chief Executive Officer and Principal Financial Officer have concluded that, as of such date, our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during the quarter ended September 30, 2023, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently a party to any material legal proceedings.

Item 1A. Risk Factors.

Our operations and financial results are subject to various risks and uncertainties, including those described below that could adversely affect our business, financial condition, results of operations, cash flows and the trading price of our common stock. You should carefully consider the following risks, together with all of the other information in this Quarterly Report on Form 10-Q, including our financial statements and the related notes included elsewhere in this Quarterly Report on Form 10-Q.

Summary of Risk Factors

We may be unable for many reasons, including those that are beyond our control, to implement our business strategy successfully. The occurrence of any single risk or any combination of risks could materially and adversely affect our business, financial condition, results of operations, cash flows and the trading price of our common stock. Some of these risks are:

- We may experience difficulties integrating Quince and EryDel's operations and realizing the expected benefits of the EryDel Acquisition.
- The Phase 3 NEAT trial of EryDex for A-T will be conducted under a protocol negotiated with FDA by EryDel and our execution of the trial may be delayed, may not be successful, and may not result in NDA approval, with adverse results for our business and share price.
- The impact and results of our previously announced strategic direction are uncertain and may not be successful.
- We have no drug candidates approved for commercial sale, we have never generated any revenue from sales, and we may never be profitable.
- We may require additional capital, and our existing stockholders may experience additional equity dilution, to fund our pursuit and consummation of the acquisition of one or more clinical-stage assets targeting debilitating and rare diseases.
- If we are unable to successfully out-license our bone targeting assets, our business could suffer.
- Because the potential rare disease target patient populations of NOV004 are small, and the addressable patient population even smaller, we may not be able to successfully out-license this asset.
- Clinical drug development is a lengthy, expensive and uncertain process. The results of preclinical studies and clinical trials are not always predictive of future results. Any drug candidate that we may advance into clinical trials or further clinical trials may not achieve favorable results in later clinical trials, if any, or receive marketing approval.
- We may not be successful in our efforts to acquire new drug candidates or to develop commercially successful drugs. If we fail to successfully identify and develop drug candidates, we may not be able to continue our operations.
- We are a biopharmaceutical company with a limited operating history, which may make it difficult to evaluate the prospects for our future viability.
- We will require substantial additional funding to finance our operations and evaluate future drug candidates. If we are unable to raise this funding when needed or on acceptable terms, we may be forced to delay, reduce or eliminate our drug development programs or other operations.
- The terms of the EIB Facility place restrictions on our operating and financial flexibility.
- We cannot be certain that the FDA or foreign regulatory authorities will permit us to proceed with any future proposed clinical trial designs. Our potential drug candidates may not receive regulatory approval, and without regulatory approval we will not be able to market our drug candidates.
- Clinical failure can occur at any stage of clinical development, and we have never conducted a Phase 3 trial or submitted an NDA before.

- If any future clinical trials of our potential drug candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States or do not otherwise produce positive results, or are put on clinical holds imposed by the FDA or similar regulatory authorities outside the United States, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our potential drug candidates.
- We have in the past and may in the future rely on third parties to conduct some of our preclinical studies and clinical trials and some aspects of our research and preclinical testing and on third-party contract manufacturing organizations to manufacture and supply our preclinical and clinical materials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research, manufacturing or testing.
- If we or any of our third-party manufacturers encounter difficulties in production of our future drug candidates, or fail to meet rigorously enforced regulatory standards, our ability to provide supply of our future drug candidates for clinical trials or for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.
- If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any drug candidates we may develop, we may not be successful in commercializing those drug candidates if and when they are approved.
- If we are unable to obtain and maintain sufficient intellectual property protection for our current drug candidates, any future drug candidates, and other proprietary technology we develop, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize drug candidates similar or identical to ours, and our ability to successfully commercialize our current drug candidate, if approved, any future drug candidates, and other proprietary technologies if approved, may be adversely affected.

We have marked with an asterisk (*) those risks described below that reflect substantive changes from, or additions to, the risks described in our Annual Report on Form 10-K for the year ended December 31, 2022.

Risks Relating to Our Business

We may experience difficulties integrating EryDel's operations and realizing the expected benefits of the EryDel Acquisition.*

The success of the EryDel Acquisition will depend in part on our ability to realize the expected operational efficiencies and associated cost synergies and anticipated business opportunities and growth prospects from the EryDel Acquisition in an efficient and effective manner. We may not be able to fully realize the operational efficiencies and associated cost synergies or leverage the potential business opportunities and growth prospects to the extent anticipated or at all.

Challenges associated with the integration may include those related to retaining and motivating executives and other key employees, blending corporate cultures, eliminating duplicative operations, and making necessary modifications to internal control over financial reporting and other policies and procedures in accordance with applicable laws. Some of these factors are outside our control, and any of them could delay or increase the cost of our integration efforts. The integration process could take longer than anticipated and could result in the loss of key employees, the disruption of each company's ongoing businesses, increased tax costs, inefficiencies, and inconsistencies in standards, controls, information technology systems, policies and procedures, any of which could adversely affect our ability to maintain relationships with employees or third parties, or our ability to achieve the anticipated benefits of the transaction, and could harm our financial performance. If we are unable to successfully integrate certain aspects of the operations of EryDel, including relevant human resource functions, or experience delays, we may incur unanticipated liabilities and be unable to fully realize the potential benefit of future revenue and other anticipated benefits resulting from the arrangement, and our business, results of operations and financial condition could be adversely affected.

The impact and results of our previously announced strategic direction are uncertain and may not be successful.*

As announced in January 2023, we intend to prioritize capital resources toward the expansion of our development pipeline through opportunistic in-licensing and acquisition of clinical-stage assets targeting debilitating and rare diseases. Since that time, our management has been actively engaged in identifying and evaluating numerous biopharmaceutical assets for their potential fit with our corporate objectives. On July 21, 2023 we entered into the EryDel Purchase Agreement with EryDel in connection with the EryDel Acquisition, which was completed on October 20, 2023.

Our Board remains dedicated to diligently deliberating upon and making informed decisions that the directors believe are in the best interests of the company and its shareholders. There can be no assurance, however, that our current strategic direction, or the

Board's evaluation of strategic alternatives, will result in any initiatives, agreements, transactions or plans that will enhance shareholder value.

We have no drug candidates approved for commercial sale, we have never generated any revenue from sales, and we may never be profitable.

We have no drug candidates approved for sale, have never generated any revenue from sales, have never been profitable and do not expect to be profitable in the foreseeable future. We have incurred net losses in each year since our inception. For the years ended December 31, 2022 and 2021, our net losses were $51.7 million and $89.9 million, respectively. We had an accumulated deficit of $310.8 million as of September 30, 2023.

Before we are able to generate any revenue, we will need to commit substantial funds to the anticipated clinical and development activities related to EryDel lead asset, as well as to in-license additional assets or acquire new drug candidates, then continue development of any drug candidates, and we may not be able to obtain sufficient funds on acceptable terms, if at all. Any additional debt financing or additional equity that we raise may contain terms that are not favorable to us and/or result in dilution to our stockholders.

We expect that it will be several years, if ever, before we may have a potential drug candidate ready for commercialization. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we pursue our current strategic direction, and seek regulatory approvals for any potential drug candidates, prepare for and begin the commercialization of any approved drug candidates, and add infrastructure and personnel to support our drug development efforts and operations as a public company. We anticipate that any such losses could be significant for the next several years. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. Further, these net losses have fluctuated significantly in the past and are expected to continue to significantly fluctuate from quarter-to-quarter or year-to-year. To become and remain profitable, we must develop and eventually commercialize a drug with significant revenue.

We may never succeed in developing a commercial drug. On January 25, 2022, the FDA placed a full clinical hold on the IND for atuzaginstat (COR388), one of our assets that has since been out-licensed. The FDA may place additional clinical holds on our current or currently contemplated clinical programs or otherwise limit our ability to proceed with other clinical programs in our pipeline, which will harm our business, financial condition, results of operations and may force us to cease our operations.

We expect to explore partnership and licensing opportunities to support the future development of NOV004, our bone targeting molecule designed to accelerate fracture repair, but we may not be able to find a suitable partner. See also the risk factor titled "*Because the potential rare disease target patient populations of NOV004 are small, and the addressable patient population even smaller, we may not be able to successfully identify potential patients to out-license this asset.*" We may also encounter other unforeseen expenses, difficulties, complications, delays and other known and unknown challenges as we pursue our current strategic direction, which includes acquiring and/or in-licensing new product candidates, such as the assets acquired in connection with the EryDel Acquisition.

There are numerous risks and uncertainties, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to generate revenues or achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and we will continue to incur substantial research and development and other expenditures to develop and market additional drug candidates.

We may require additional capital, and our existing stockholders may experience additional equity dilution, to fund our pursuit and consummation of the acquisition of one or more clinical-stage assets targeting debilitating and rare diseases.

The pursuit of our strategy to acquire one or more clinical-stage assets targeting debilitating and rare diseases involves significant management time, effort and associated expense, and if such assets are identified, will require us to incur significant additional expenses to consummate. Additionally, in connection with the EryDel Acquisition, we are required to make payments to EryDel Shareholders if we achieve certain milestones as provided for in the Purchase Agreement and may need additional funding to make such payments. Moreover, we expect to require substantial additional funding to finance such acquisitions and to advance the development and optimize the commercialization of such assets, including the assets acquired in connection with the EryDel Acquisition, and there can be no assurance that such additional funding will be available on terms that are acceptable to us, or at all. If adequate funds are not available on a timely basis, we may not be able to effectively implement our strategic plan.

We may seek to raise any necessary funds through public or private equity offerings, debt financings or strategic alliances and licensing arrangements. We may not be able to obtain additional financing on terms favorable to us, if at all. General market conditions may make it very difficult for us to seek financing from the capital markets.

Our acquisition strategy involves numerous risks and uncertainties, including intense competition for suitable acquisition targets, which could increase valuations or adversely affect our ability to consummate deals on favorable or acceptable terms, the potential unavailability of financial resources necessary to consummate acquisitions in the future, the risk that we improperly value and price a target, the inability to identify all of the risks and liabilities inherent in a target company notwithstanding our due diligence efforts, the diversion of management's attention from the operations of our business and strain on our existing personnel, increased leverage due to additional debt financing that may be required to complete an acquisition, dilution of our stockholder's net current book value per share if we issue additional equity securities to finance an acquisition, difficulties in identifying suitable acquisition targets or in completing any transactions identified on sufficiently favorable terms and the need to obtain regulatory or other governmental approvals that may be necessary to complete acquisitions.

Our stockholders may realize little or no value from the divestiture of our legacy assets or potential out-license of NOV004, and as a result our stock price may decline, we could be subject to litigation, and our business may be adversely affected.

We have recently sold our legacy small molecule protease inhibitor portfolio to Lighthouse, which is a newly organized, private development stage company in the start-up phase, and has only recently commenced its operations. There is currently no existing public market for the shares of Lighthouse's common stock, and there can be no assurance that an active public market will ever develop. The absence of an active public market for these securities would make it difficult for us to sell the shares of Lighthouse's common stock and realize any value from them. To date, Lighthouse's operations have been primarily limited to organizing and staffing its company and completing the acquisition of our legacy assets. Accordingly, it is difficult if not impossible to predict Lighthouse's future performance or to evaluate its business and prospects, or ability to develop our legacy assets. For these and other reasons, our stockholders may realize little or no value from the divestiture of our legacy assets.

The divestiture of our legacy assets or recently announced change in our corporate strategy, including potential partnership or licensing of NOV004, could result in litigation against us, including litigation arising from or related to the value, received in the sale of our legacy assets to Lighthouse. For example, some of our investors purchased shares of our common stock because they were interested in the opportunities presented by our small molecule protease inhibitor portfolio, others because they were interested in our bone-targeting drug platform. Thus, certain stockholders may attribute substantial financial value to our legacy assets or NOV004. If our stockholders believe that the financial value which is or may be received by us or them from the divestiture of our assets is inadequate, our stock price may decline and litigation may occur. As a result of these and other factors, we may be exposed to a number of risks, including declines or fluctuations in our stock price, additional legal fees, and distractions to our management caused by activities undertaken in connection with resolving any disputes related to these transactions. The occurrence of any one or more of the above could have an adverse impact on our business and financial condition.

Our future results could suffer if we do not effectively manage our operations.

In connection with our new strategic pursuits, we may expand our size and operations through acquisitions or other strategic transactions, including through the EryDel Acquisition. Our future success depends, in part, upon our ability to manage such expanded business, which may pose substantial challenges for management, including challenges related to the management and monitoring of new operations and associated increased costs and complexity. There can be no assurances that we will be successful or that we will realize the expected synergies and other benefits anticipated from any future acquisitions or strategic transactions that we may undertake in the future.

Our financial results have been in the past and may in the future be adversely by impairment charges from the recording of goodwill and intangible assets.*

Our financial results have been in the past and may in the future be adversely affected by impairment charges from the recording of goodwill and intangible assets incurred in connection with acquisitions. For example, we incurred a $0.8 million goodwill impairment charge in the quarter ended September 30, 2022 and a $5.9 million IPR&D Intangible Asset impairment charge for the quarter ended March 31, 2023 in connection with the Novosteo Acquisition. Further, our failure to identify or accurately assess the magnitude of necessary technology investments we assumed as a result of the Novosteo Acquisition could result in unexpected litigation or regulatory exposure, unfavorable accounting charges, a loss of anticipated tax benefits or other adverse effects on our business, operating results or financial condition.

The success of our business depends in part on our ability to successfully acquire or in-license new product candidates.

The success of our business depends in part on our ability to successfully acquire or in-license new product candidates, including the assets acquired in connection with the EryDel Acquisition. Our acquisition and in-licensing efforts focus on identifying

assets in development by third parties across a diverse range of therapeutic areas that, in our view, are underserved or undervalued. We may decide to proceed with the development of a product candidate and later determine that the more costly and time intensive trials do not support the initial value the product candidate was thought to hold. Even if a product candidate does prove to be valuable, its value may be less than anticipated at the time of investment. We may also face competition for attractive investment opportunities. A number of entities compete with us for such opportunities, many of which have considerably greater financial and technical resources. If we are unable to identify a sufficient number of such product candidates, or if the product candidates that we identify do not prove to be as valuable as anticipated, we will not be able to generate returns and implement our investment strategy and our business and results of operations may suffer materially.

If we fail to properly evaluate potential acquisitions, in-licenses, investments or other transactions associated with the creation of new research and development programs or the maintenance of existing ones, we might not achieve the anticipated benefits of any such transaction.*

We have developed our innovative bone-targeting drug platform and lead compound NOV004 for development for rare skeletal diseases, bone fractures, and injury. NOV004 is a systemically administered bone anabolic peptide engineered to target and concentrate at bone fracture sites. We are actively exploring partnership and licensing opportunities, including out-licenses, for our now suspended development program related to NOV004. We face significant competition in our pursuit of these opportunities, and any arrangements will likely be complex and time-consuming to negotiate and document. If we are unable to identify suitable partners for our indications, or if we are required to enter into agreements with such partners on unfavorable terms, our business and prospects could materially suffer.

Risks Related to Our Business and the Development of Our Drug Candidates

The Phase 3 NEAT trial of EryDex for A-T will be conducted under a protocol negotiated with FDA by EryDel and our execution of the trial may be delayed, may not be successful, and may not result in NDA approval, with adverse results for our business and share price.*

With the acquisition of our Phase 3 lead asset, EryDex, we intend to initiate the Phase 3 NEAT trial in the first half of 2024. The NEAT protocol is the subject of a Special Protocol Assessment, or SPA, agreement with FDA. The FDA may revoke or alter its SPA agreement under the following circumstances:

- public health concerns emerge that were unrecognized at the time of the protocol assessment, or the director of the review division determines that a substantial scientific issue essential to determining safety or efficacy has been identified after testing has begun;
- a sponsor fails to follow a protocol that was agreed upon with the FDA; or
- the relevant data, assumptions, or information provided by the sponsor in a request for SPA change, are found to be false statements or misstatements, or are found to omit relevant facts.

A documented SPA may be modified, and such modification will be deemed binding on the FDA review division, except under the circumstances described above, if the FDA and the sponsor agree in writing to modify the protocol and such modification is intended to improve the study. An SPA, however, does not guarantee that a trial will be successful, and our execution of the Phase 3 NEAT trial may be delayed and even if successful may not result in approval by the FDA.

If we are unable to successfully out-license our bone targeting assets, our business could suffer.*

We have developed our innovative bone-targeting drug platform and lead compound NOV004 for development for rare skeletal diseases, bone fractures, and injury. NOV004 is a systemically administered bone anabolic peptide engineered to target and concentrate at bone fracture sites. Currently, we intend to explore partnership and licensing opportunities to support the future development of NOV004. However, we may not be able to identify suitable partners. If we are unable to identify suitable partners for our indications, or if we are required to enter into agreements with such partners on unfavorable terms, our business and prospects could suffer.

Because the potential rare disease target patient populations of NOV004 are small, and the addressable patient population even smaller, we may not be able to successfully out-license this asset.

NOV004 is a precision bone growth molecule for rare disease. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with NOV004, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, or patient foundations, and may prove to be incorrect or contain errors. New studies have in the past and may continue to change the estimated incidence or prevalence of these diseases. We cannot accurately predict the number of patients for whom treatment might be possible. Additionally, since the potentially addressable patient population for this product candidates is limited, even if we successfully license these assets, and our partners obtain commercial approval, they may not be able to achieve significant market share for NOV004. Because the potential target populations are very small, we may not realize any significant return from the potential sale of this asset.

Clinical drug development is a lengthy, expensive and uncertain process. The results of preclinical studies and early clinical trials are not always predictive of future results. Any drug candidate that we may advance into clinical trials may not achieve favorable results in later clinical trials, if any, or receive marketing approval.

The research and development of drugs is extremely risky. Only a small percentage of drug candidates that enter the development process ever receive marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of any drug candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain.

The results of preclinical studies and completed clinical trials are not necessarily predictive of future results, and our current drug candidate may not be further developed or have favorable results in later studies or trials. Clinical trial failure may result from a multitude of factors including, but not limited to, flaws in study design, dose selection, placebo effect, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits. As such, failure in clinical trials can occur at any stage of testing. A number of companies in the pharmaceutical industry have suffered setbacks in the advancement of their drug candidates into later-stage clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding results in earlier preclinical studies or clinical trials. In addition, data obtained from preclinical trials and clinical trials are susceptible to varying interpretations, and regulatory authorities may not interpret our data as favorably as we do, which may further delay, limit or prevent development efforts, clinical trials or marketing approval. Furthermore, as more competing drug candidates within a particular class of drugs proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change.

If we are unable to complete preclinical studies or clinical trials of any future drug candidates, due to safety or efficacy concerns, or if the results of these trials are not sufficient to convince regulatory authorities of their safety or efficacy, we will not be able to obtain marketing approval for commercialization on a timely basis or at all. Even if we are able to obtain marketing approval for our current and any future drug candidates, those approvals may be for indications or dose levels that deviate from our desired approach or may contain other limitations that would adversely affect our ability to generate revenue from sales of those drug candidates. Moreover, if we are not able to differentiate our drug candidate against other approved drug candidates within the same class of drugs, or if any of the other circumstances described above occur, our business would be harmed and our ability to generate revenue from that class of drugs would be severely impaired.

We may not be successful in our efforts to acquire new drug candidates or to develop commercially successful drugs. If we fail to successfully identify and develop drug candidates, we may not be able to continue our operations.

Our strategy is to identify and pursue clinical development of drug candidates. Identifying, developing, obtaining regulatory approval and commercializing drug candidates will require substantial additional funding and is prone to the risks of failure inherent in drug development. We cannot provide you any assurance that we will be able to successfully identify or acquire drug candidates, advance any drug candidates through the development process, successfully commercialize any such drug candidates, if approved, or assemble sufficient resources to identify, acquire, develop or, if approved, commercialize drug candidates. If we are unable to successfully identify, acquire, develop and commercialize drug candidates, we may not be able to continue our operations.

We will incur additional costs and may experience delays in completing, or ultimately be unable to complete, the development and commercialization of our potential drug candidates.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our potential drug candidates, including:

- regulatory authorities, institutional review boards (“IRBs”) or ethics committees (“ECs”) may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site or we may fail to reach a consensus with regulatory authorities on trial design;

- regulatory authorities in jurisdictions in which we seek to conduct clinical trials may differ from each other on our trial design, and it may be difficult or impossible to satisfy all such authorities with one approach;
- we may not be able to generate sufficient preclinical data to support clinical development for potential drug candidates;
- we may require preclinical studies or manufacturing of drug supplies for our potential drug candidates, which may delay our timeline for the clinical development for our potential drug candidates;
- we may experience delays in reaching a consensus with regulatory agencies on preclinical and clinical study design;
- we may not be able to obtain appropriate or sufficient test agents or preclinical animal models in connection with the indications out potential drug candidates are meant to address;
- we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different contract research organizations ("CROs") and trial sites;
- clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or regulatory authorities may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate;
- enrollment in our clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- changes to clinical trial protocols;
- our third-party contractors, including clinical investigators, contract manufacturers and vendors may fail to comply with applicable regulatory requirements, lose their licenses or permits, or otherwise fail, or lose the ability to, meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials of our drug candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- regulatory authorities or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our drug candidates may be greater than we anticipate, and we may lack adequate funding to continue one or more clinical trials;
- the supply or quality of our drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate;
- our drug candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulatory authorities or institutional review boards to suspend or terminate the trials;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies; and
- the occurrence of natural disasters, such as earthquakes, tsunamis, power shortages or outages, floods, or monsoons, public health crises, such as pandemics and epidemics, political crisis, such as terrorism, war, political instability or other conflict, cyberattacks, or other events outside of our control occurring at or around our clinical trials sites in the United States, Australia or Europe.

Preclinical studies and clinical trials are expensive and time consuming, additional or unsuccessful clinical trials could cause our clinical development activities to be delayed or otherwise adversely affected.

The risk of failure is high for any potential drug candidates we may acquire that are in clinical and preclinical development. The clinical trials and manufacturing of our potential drug candidates are, and the manufacturing and marketing of our potential drug candidates, if approved, will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and market our drug candidates. Before obtaining regulatory approvals for the commercial sale of any of our potential drug candidates, we must demonstrate thorough lengthy, complex and expensive preclinical testing and clinical trials that our potential drug candidates are both safe and effective for use in each target indication. We may not be able to develop a trial design that the FDA and other foreign regulatory authorities can accept. Each potential drug candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use.

Clinical trials are expensive and can take many years to complete, and their outcomes are inherently uncertain. We cannot guarantee that any future clinical trials will be conducted as planned or completed on schedule, if at all. Failure can occur at any time during the clinical trial process. Even if any future clinical trials are completed as planned, we cannot be certain that their results will support the safety and effectiveness of our potential product candidates for their targeted indications or support continued clinical development of such product candidates. Our ongoing and any future clinical trial results may not be successful.

In addition, even if such trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our potential drug candidates for approval. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our potential drug candidates.

If we are required to conduct preclinical studies, clinical trials or other testing of our potential drug candidates beyond those that we currently contemplate, if we are unable to successfully complete preclinical studies, clinical trials of our potential drug candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our potential drug candidates;
- not obtain marketing approval at all;
- obtain approval for indications, dosages or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the medicine removed from the market after obtaining marketing approval.

Drug development costs will also increase if we experience delays in testing or in obtaining marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be amended or will be completed on schedule, or at all. Significant preclinical studies and clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our potential drug candidates, could allow our competitors to bring drug candidates to market before we do, and could impair our ability to successfully commercialize our potential drug candidates, if approved, any of which may harm our business and results of operations. In addition, many of the factors that cause, or lead to a delay in the commencement or completion of, clinical trials may also ultimately lead to termination or suspension of a clinical trial. Any of these occurrences may harm our business, financial condition and prospects significantly. Any termination of any clinical trial of our potential drug candidates will harm our commercial prospects and our ability to generate revenues.

Risks Relating Our Financial Position

We are a biopharmaceutical company with a limited operating history, which may make it difficult to evaluate the prospects for our future viability.*

From our inception, we have been focused on novel therapeutic approaches to improve the lives of patients diagnosed with Alzheimer's and other degenerative diseases. After the Novosteo Acquisition in 2022, we shifted our operational focus on the development of our bone-targeting drug platform and lead compound NOV004 for development for rare skeletal diseases, bone fractures, and injury. In January 2023, we made a strategic decision to out-license our bone-targeting drug platform and prioritize capital resources toward the expansion of our development pipeline through the completion the acquisition of EryDel in October 2023. We have a limited operating history, which may make it difficult to evaluate the success of our business to date and assess our future viability. Drug development is a highly uncertain undertaking and involves a substantial degree of risk. To date, we have only initiated one late stage clinical trial, and have not obtained marketing approval for any drug candidate, manufactured a commercial scale drug candidate, arranged for a third party to do so on our behalf, or conducted sales and marketing activities necessary for successful drug candidate commercialization. Our short operating history as a company makes any assessment of our future success and viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early-stage biopharmaceutical companies in rapidly evolving fields, and we have not yet demonstrated an ability to overcome such risks and difficulties successfully. If we do not address these risks and difficulties successfully, our business will suffer.

We will require substantial additional funding to finance our operations and evaluate future drug candidates. If we are unable to raise this funding when needed or on acceptable terms, we may be forced to delay, reduce or eliminate our drug development programs or other operations.

Since our inception, we have used substantial amounts of cash to fund our operations, and we expect our expenses to increase substantially in the foreseeable future in connection with our ongoing activities, particularly as we evaluate and develop potential drug candidates. In addition, if we obtain marketing approval for any future drug candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution.

Accordingly, we will need to obtain substantial additional funding in order to fully execute on our corporate strategy. As of September 30, 2023, we had $83.2 million in cash, cash equivalents and investments. Our balance sheet includes publicly-traded corporate debt securities. We may be required to recognize impairments in the value of these investments if the relevant companies are materially adversely effected, become unable to repay debt securities when due, or experience credit rating downgrades, or if the public trading price of these securities decreases.

We believe that our existing capital resources will be sufficient to fund our projected operations, which would include anticipated clinical and development activities related to EryDel's lead asset through potential NDA submission to the FDA, assuming positive results from the Phase 3 NEAT trial, through at least 2026, but does not include any costs or cash expenditures associated with any additional potential asset acquisition. However, changing circumstances may cause us to increase our spending significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may need to raise additional funds sooner than we anticipate if we choose to expand more rapidly than we presently anticipate. The amount and timing of our future funding requirements will depend on many factors, some of which are outside of our control, including but not limited to:

- our ability to successfully identify partnership and licensing opportunities to support the future development of NOV004;
- the outcome, costs and timing of seeking and obtaining FDA and any other regulatory approvals;
- the number and characteristics of drug candidates that we acquired or pursue;
- our ability to manufacture sufficient quantities of our potential drug candidates and devices;
- our need to expand our research and development activities;
- the costs associated with securing and establishing commercialization and manufacturing capabilities;
- the costs of acquiring, licensing or investing in businesses, drug candidates and technologies;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to retain management and hire scientific and clinical personnel;
- the effect of competing drugs and drug candidates and other market developments;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and
- the economic and other terms, timing of and success of any collaboration, licensing or other arrangements into which we may enter in the future.

Additional funding may not be available to us on acceptable terms or at all. Any such funding may result in dilution to stockholders, imposition of debt covenants and repayment obligations, or other restrictions that may affect our business. We also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to some of our technologies or drug candidates or otherwise agree to terms unfavorable to us. Additionally, while the potential global economic impact and the continuing effects of the COVID-19 pandemic may be difficult to assess or predict, a widespread pandemic could result in significant long-term disruption of global financial markets, which could in the future reduce our ability to access capital and negatively affect our liquidity. In addition, the trading prices for our common stock and other biopharmaceutical companies, as well as the broader equity and debt markets, have been highly volatile as a result of the COVID-19 pandemic and the resulting impact on economic activity.

The terms of the EIB Facility place restrictions on our operating and financial flexibility.

In connection with the EIB Facility, we are subject to operating restrictions and covenants that restrict our ability to finance our operations, engage in business activities or expand or fully pursue its business strategies. For example, unless we get approval from EIB, the EIB Facility limits our ability to, among other things:

- incur additional debt or provide guarantees in respect of debt;
- incur liens;
- make investments, acquisitions, loans or advances;
- sell assets;
- make distributions to equity holders, including dividends and distributions on, and redemptions, repurchases or retirement of, our capital stock;
- enter into certain hedging transactions;
- enter into fundamental changes, including mergers and consolidations;
- enter into transactions with affiliates;
- change the nature of our business; and
- change our management.

In addition, the EIB Facility requires that we meet certain reporting and operating covenants, including an obligation to maintain a certain minimum unrestricted balance of cash or cash equivalents. Our ability to comply with these covenants may be affected by events beyond our control, and we may not be able to meet those covenants.

The EIB Facility includes customary events of default, including failure to pay principal, interest or certain other amounts when due; material inaccuracy of representations and warranties; breach of covenants; cross-default to other indebtedness (resulting in a right of the other lender to accelerate such indebtedness after giving effect to any grace periods); certain bankruptcy and insolvency events; certain undischarged judgments; material adverse change. A breach of any of these covenants could result in an event of default under the EIB Facility. If an event of default occurs and is ongoing under the terms of the Finance, EIB may accelerate all of the obligations of EryDel thereunder and demand payment from us pursuant to the guarantees. Any declaration by the lender of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline.

Unstable market and global economic conditions, including adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions, may have adverse consequences on our business, financial condition and stock price.*

The global credit and financial markets have experienced volatility, including as a result of the COVID-19 pandemic, changes in interest rates, and economic inflation, which has included diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, high inflation, uncertainty about economic stability and changes in unemployment rates. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, acts of terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also continue to adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could heighten market and economic instability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our royalty aggregator strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. Failure to secure any necessary financing in a timely manner could have a material adverse effect on our growth strategy, financial performance and stock price.

We regularly maintain cash balances at third-party financial institutions in excess of the FDIC insurance limit. Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have arrangements directly, or the financial services industry or economy in general. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

Risks Relating to Regulatory Review and Approval of Our Drug Candidates and Other Legal Compliance Matters

We cannot be certain that the FDA or foreign regulatory authorities will permit us to proceed with any future proposed clinical trial designs. Our potential drug candidates may not receive regulatory approval, and without regulatory approval we will not be able to market our drug candidates.

We currently have no drug candidates approved for sale and we cannot guarantee that we will ever have marketable drug candidates. Our ability to generate revenue related to sales, if ever, will depend on the successful development and regulatory approval of our potential product candidates.

The development of a drug candidate and issues relating to its approval and marketing are subject to extensive regulation by the FDA in the United States and regulatory authorities in other countries, with regulations differing from country to country. We are not permitted to market any potential drug candidates in the United States until we receive approval of an NDA from the FDA. We have not submitted any marketing applications for a drug candidate.

NDAs must include extensive preclinical and clinical data and supporting information to establish the drug candidate's safety and effectiveness for each desired indication. NDAs must also include significant information regarding the chemistry, manufacturing and controls for the drug. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. The FDA review processes can take years to complete and approval is never guaranteed. If we submit an NDA to the FDA, the FDA must decide whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the FDA. Regulators of other jurisdictions have their own procedures for approval of drug candidates. Even if a drug is approved, the FDA may limit the indications for which the drug may be marketed, require extensive warnings on the drug labeling or require expensive and time-consuming clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States also have requirements for approval of drug candidates with which we must comply prior to marketing in those countries. Obtaining regulatory approval for marketing of a drug candidate in one country does not ensure that we will be able to obtain regulatory approval in any other country. In addition, delays in approvals or rejections of marketing applications in the United States or other countries may be based upon many factors, including regulatory requests for additional analyses, reports, data, preclinical studies and clinical trials, regulatory questions regarding different interpretations of data and results, changes in regulatory policy during the period of drug development and the emergence of new information regarding our drug candidates or other drug candidates. Also, regulatory approval for any of our drug candidates may be withdrawn.

Clinical failure can occur at any stage of clinical development, and we have never conducted a Phase 3 trial or submitted an NDA before.

The FDA or other foreign regulatory authorities may limit our ability to proceed with potential clinical programs, which could have a materially adverse impact on us. The submission of a successful NDA is a complicated process. As an organization, we have never conducted a registrational clinical trial and have limited experience in preparing, submitting and prosecuting regulatory filings, and have not submitted an NDA. Failure to commence or complete, or delays in, our planned clinical trials would prevent us from or delay us in seeking approval for, and if approved, commercializing our drug candidates, and failure to successfully complete any of these activities in a timely manner for any of our drug candidates could have a material adverse impact on our business and financial performance. The commencement, enrollment and completion of clinical trials can be delayed or suspended for a variety of reasons, including:

- inability to obtain sufficient funds required for a clinical trial;
- inability to reach agreements on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical holds, other regulatory objections to commencing or continuing a clinical trial or the inability to obtain regulatory approval to commence a clinical trial in countries that require such approvals;
- discussions with the FDA or non-U.S. regulators regarding the scope or design of our clinical trials;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indications targeted by our drug candidates;
- inability to obtain approval from IRBs to conduct a clinical trial at their respective sites;
- severe or unexpected drug-related adverse effects experienced by patients, which have resulted and may result in a full or partial clinical hold by the FDA or non-U.S. regulators;
- inability to timely manufacture sufficient quantities of the drug candidate or devices required for a clinical trial;

- difficulty recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including meeting the enrollment criteria for our study and competition from other clinical trial programs for the same indications as our drug candidates;
- inability to retain enrolled patients after a clinical trial is underway; and
- enrollment may be delayed or interrupted or patients may drop out of clinical trials due to or the fear of natural disasters, such as earthquakes, tsunamis, power shortages or outages, floods, or monsoons, public health crises, such as pandemics and epidemics, political crisis, such as terrorism, war, political instability or other conflict, cyberattacks, or other events outside of our control occurring at or around our clinical trials sites in the United States or Europe. For example, the coronavirus outbreak may delay or impede enrollment in our clinical trials due to prioritization of hospital resources toward the outbreak, and some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, which would delay our ability to release clinical results and could impact our product candidates testing, development and timelines.

In addition, the design of a clinical trial can determine whether its results will support approval of a drug and flaws in the design of a clinical trial may not become apparent until the clinical trial is well-advanced. Changes in regulatory requirements and guidance may also occur and we may need to amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. Amendments may require us to resubmit clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial.

In addition, if we are required to conduct additional clinical trials or other preclinical studies of our drug candidates beyond those contemplated, our ability to obtain regulatory approval of these drug candidates and generate revenue from their sales would be similarly harmed.

If any future clinical trials of our potential drug candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States or do not otherwise produce positive results, or are put on clinical holds imposed by the FDA or similar regulatory authorities outside the United States, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our potential drug candidates.

Before obtaining regulatory approvals for the commercial sale of any of our potential drug candidates, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our potential drug candidates are both safe and effective for use in each target indication. Each drug candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies of our potential drug candidates may not be predictive of the results of early-stage or later-stage clinical trials, and results of early clinical trials of our potential drug candidates may not be predictive of the results of later-stage clinical trials. The results of clinical trials in one set of patients or disease indications may not be predictive of those obtained in another. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. This is particularly true in degenerative diseases, where failure rates historically have been higher than in many other disease areas. Most drug candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our drug candidates for approval. Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or other regulatory authorities. The FDA or other regulatory authorities may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected the integrity of the study. The FDA or other regulatory authorities may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or other regulatory authorities, as the case may be, and may ultimately lead to the denial of marketing approval of any of our drug candidates. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory

authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our drug candidates. Even if regulatory approval is secured for any of our drug candidates, the terms of such approval may limit the scope and use of our drug candidate, which may also limit its commercial potential.

We have in the past and may in the future rely on third parties to conduct some of our preclinical studies and clinical trials and some aspects of our research and preclinical testing and on third-party contract manufacturing organizations to manufacture and supply our preclinical and clinical materials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research, manufacturing or testing.

We rely and expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct some aspects of our research and preclinical testing and our clinical trials. We also rely on third-party contract manufacturing organizations to manufacture and supply our preclinical and clinical materials. Any of these third parties may terminate their engagements with us or be unable to fulfill their contractual obligations. If we need to enter into alternative arrangements, it would delay our future drug development activities.

Our reliance on these third parties for research and development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with current good clinical practice regulations ("GCP") for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible, reproducible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. We also are required to register any future clinical trials and post the results of completed clinical trials on a government-sponsored database within certain timeframes. Failure to do so can result in fines, adverse publicity, and civil and criminal sanctions.

Reliance on third-party manufacturers entails additional risks, such as the possible breach of the manufacturing agreement by the third party, the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us and reliance on the third party for regulatory compliance, quality assurance, safety and related reporting. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for any drug candidates we may develop and will not be able to, or may be delayed in our efforts to, successfully commercialize our medicines.

We also expect to rely on other third parties to store and distribute drug supplies for our future clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of any drug candidates we may develop or commercialization of our medicines, producing additional losses and depriving us of potential drug revenue.

If we or any of our third-party manufacturers encounter difficulties in production of our future drug candidates, or fail to meet rigorously enforced regulatory standards, our ability to provide supply of our future drug candidates for clinical trials or for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

The processes involved in manufacturing our potential drug candidates are highly regulated and subject to multiple risks. As drug candidates are developed through preclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our potential drug candidates to perform differently and affect the results of planned clinical trials or other future clinical trials.

In order to conduct clinical trials of our potential drug candidates, or supply future commercial drug candidates or devices, if approved, we will need to manufacture them in small and large quantities. Our manufacturing partners may be unable to successfully modify or scale-up the manufacturing capacity for any of our drug candidates or devices in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If our manufacturing partners are unable to successfully scale-up the manufacture of our potential drug candidates or devices in sufficient quality and quantity, the development, testing and clinical trials of that drug candidate may be delayed or become infeasible, and regulatory approval or commercial launch of any resulting drug may be delayed or not obtained, which could significantly harm our business. The same risks would apply to our internal manufacturing facilities, should we in the future decide to build internal manufacturing capacity. In addition, building internal manufacturing capacity

would carry significant risks in terms of being able to plan, design and execute on a complex project to build manufacturing facilities in a timely and cost-efficient manner.

In addition, the manufacturing process for any potential drug candidates that we may develop is subject to FDA and foreign regulatory requirements, and continuous oversight, and we will need to contract with manufacturers who can meet all applicable FDA and foreign regulatory authority requirements, including complying with current good manufacturing practices ("cGMPs"), on an ongoing basis. If we or our third-party manufacturers are unable to reliably produce drug candidates in accordance with the requirements of the FDA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such future drug candidates. Even if we obtain regulatory approval for any of our potential drug candidates, there is no assurance that either we or our third party contract manufacturers will be able to manufacture the approved drug in accordance with the requirements of the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the drug, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our drug candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects.

If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any drug candidates we may develop, we may not be successful in commercializing those drug candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing, or distribution of pharmaceutical drug candidates or devices. To achieve commercial success for any approved potential drug candidate for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to third parties. In the future, we may choose to build a focused sales, marketing, and commercial support infrastructure to sell, or participate in sales activities with collaborators for, some of our potential drug candidates if and when they are approved.

There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, factors that may inhibit our efforts to commercialize any potential drug candidates, if and when approved, whether alone or in collaboration with others:

- our inability to recruit and retain adequate numbers of effective sales, marketing, coverage or reimbursement, customer service, medical affairs, and other support personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future approved drug candidates;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement, and other acceptance by payors;
- the inability to price our drug candidates at a sufficient price point to ensure an adequate and attractive level of profitability;
- the pricing of our products, particularly as compared to alternative treatments;
- availability of alternative effective treatments for indications our therapeutic candidates are intended to treat and the relative risks, benefits and costs of those treatments;
- restricted or closed distribution channels that make it difficult to distribute our drug candidates to segments of the patient population;
- the lack of complementary drug candidates to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive drug candidate lines; and
- unforeseen costs and expenses associated with creating an independent commercialization organization.

If the commercial launch of a future drug candidate for which we recruit a sales force and establish marketing and other commercialization capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our commercialization personnel.

If we enter into arrangements with third parties to perform sales, marketing, commercial support, and distribution services, our sales revenue or the profitability of sales revenue may be lower than if we were to market and sell any drug candidates we may develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to commercialize our

potential drug candidates or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our drug candidates effectively. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our potential drug candidates if approved in the future.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our drug candidates.

We face an inherent risk of product liability as a result of the clinical testing of our drug candidates and will face an even greater risk when and if we commercialize any drug candidates. For example, we may be sued if our drug candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, early access program, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Product liability claims may be brought against us by participants enrolled in our clinical trials, patients, health care providers or others using, administering or selling our drug candidates. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit testing and commercialization of our drug candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased or interrupted demand for our drug candidates;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- drug recalls, withdrawals or labeling, marketing or promotional restrictions;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any drug candidate; and
- a decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of drug candidates we develop, alone or with potential collaborators. Our insurance policies may have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

We may be exposed to a variety of international risks that could materially adversely affect our business.

Our business is subject to risks associated with conducting business internationally. Some of our suppliers and clinical trial centers are located outside of the United States. We may enter into agreements with third parties for the development and commercialization of drug candidates in international markets. International business relationships will subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including:

- differing regulatory requirements for drug approvals internationally;
- rejection or qualification of foreign clinical trial data by the competent authorities of other countries;
- complexities and difficulties in obtaining, maintaining, protecting and enforcing our intellectual property;

- potential third-party patent rights in countries outside of the United States;
- the potential for so-called “parallel importing,” which is what occurs when a local seller, faced with relatively high local prices, opts to import goods from another jurisdiction with relatively low prices, rather than buying them locally;
- the potential for so-called “parallel exporting,” which is what occurs when a local seller buys goods meant for the locals and sells the goods for a higher price in another country, potentially causing or aggravating supply problems;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, bank failures, or political instability, particularly in non-U.S. economies and markets, including several countries in Europe;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- regulatory and compliance risks that relate to anti-corruption compliance and record-keeping that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its accounting provisions or its anti-bribery provisions or provisions of anti-corruption or anti-bribery laws in other countries;
- taxes in other countries;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, public health crises, such as pandemics and epidemics, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

Any of these factors could harm our ongoing international clinical operations and supply chain, as well as any future international expansion and operations and, consequently, our business, financial condition, prospects and results of operations.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants, and the loss of such persons could negatively impact the operations of the company.

We may not be able to attract or retain qualified management, finance, scientific and clinical personnel and consultants due to the intense competition for qualified personnel and consultants among biotechnology, pharmaceutical and other businesses or any other circumstances that would cause them no longer to provide their professional services to us in the near future. If we are not able to attract and retain necessary personnel and consultants to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy. In addition, we may need to adjust the size of our workforce as a result of changes to our expectations for our business, which can result in diversion of management attention, disruptions to our business, and related expenses.

In addition, we recently announced a reduction in force, impacting a number of employees. Any further reduction in force may yield unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond the intended reduction in force, the distraction of employees, reduced employee morale and could adversely affect our reputation as an employer, which could make it more difficult for us to hire new employees in the future and increase the risk that we may not achieve the anticipated benefits from the cost reduction program.

Our industry has experienced a high rate of turnover of management personnel in recent years. Potential changes in management could be disruptive to our business and may also result in our loss of unique skills and loss of knowledge about our business. Such turnover may also result in the departure of other existing employees or partners.

Replacing executive officers, key employees and consultants may be difficult and may take an extended period because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize drug candidates successfully. Competition to hire and retain employees and consultants from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel and consultants. Our failure to retain or replace key personnel or consultants could materially harm our business. Additionally, the members of our management team have limited experience managing a public company, interacting with public company investors, and complying with the increasingly complex laws, rules and regulations that specifically govern public companies, which could cause our management to have to expend time and resources helping them become familiar with such requirements. We may lose our ability to implement our business strategy successfully and could be seriously harmed. Any of our executive officers or key employees or consultants may terminate their employment at any time.

We have scientific and clinical advisors and consultants who assist us in formulating our research, development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. Non-compete agreements are not permissible or are limited by law in certain jurisdictions and, even where they are permitted, these individuals typically will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, our advisors may have arrangements with other companies to assist those companies in developing drug candidates or technologies that may compete with ours.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading, which could significantly harm our business.

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and non-U.S. regulators, provide accurate information to the FDA and non-U.S. regulators, comply with health care fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, products liability and directors' and officers' insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions, which could include civil or criminal penalties, private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We and any of our potential collaborators may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and

security requirements under the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"). Depending on the facts and circumstances, we could be subject to civil, criminal, and administrative penalties if we violate HIPAA.

Several foreign jurisdictions, including the European Union (the "EU") its member states, the United Kingdom and Australia, among others, have adopted legislation and regulations that increase or change the requirements governing the collection, use, disclosure and transfer of the personal information of individuals in these jurisdictions. These laws and regulations are complex and change frequently, at times due to changes in political climate, and existing laws and regulations are subject to different and conflicting interpretations, which adds to the complexity of processing personal data from these jurisdictions. These laws have the potential to increase costs of compliance, risks of noncompliance and penalties for noncompliance.

The General Data Protection Regulation ("GDPR") imposes numerous new requirements for the collection, use and disclosure of personal information, including more stringent requirements relating to consent and the information that must be shared with data subjects about how their personal information is used, the obligation to notify regulatory authorities and affected individuals of personal data breaches, extensive new internal privacy governance obligations, and obligations to honor expanded rights of individuals in relation to their personal information (for example, the right to access, correct and delete their data). In addition, the GDPR generally maintains restrictions on cross-border data transfer. The GDPR will increase our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional potential mechanisms to ensure compliance.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects, employees and other individuals about whom we or our potential collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Changes in healthcare law and implementing regulations, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict, and may have a significant adverse effect on our business and results of operations.*

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of drug candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any drug candidates for which we obtain marketing approval. Among policy makers and payors in the United States and elsewhere, including in the EU, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively the "ACA") substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures will impact the ACA and our business. Other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our existing products that we successfully commercialize or to successfully commercialize our drug candidates, if approved. In addition to the ACA, there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to keep healthcare costs down while expanding individual healthcare benefits. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is unclear how these or similar policy initiatives will impact the ACA and our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011 and subsequent

laws, which began in 2013 and, due to subsequent legislative amendments to the statute, will remain in effect until 2032, unless additional Congressional action is taken. New laws may result in additional reductions in Medicare and other healthcare funding, which may adversely affect customer demand and affordability for our drug candidates and, accordingly, the results of our financial operations.

Also, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed drug candidates, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the Department of health and Human Services (HHS) released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. Further, the IRA will, among other things (i) allow HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the "negotiated fair price" under the law and (ii) impose rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. It is currently unclear how the IRA will be effectuated but is likely to have a significant impact on the pharmaceutical industry. Further, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Centers for Medicare & Medicaid Services (CMS) Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved drug candidate. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drug candidates, once marketing approval is obtained.

Our ability to successfully commercialize any drugs that we develop depends in part on the extent to which coverage and adequate reimbursement are available from government health administration authorities, private health insurers, and other organizations.

Our ability to successfully commercialize any drugs that we develop depends in part on the extent to which coverage and adequate reimbursement are available from government health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, each individually decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Government authorities currently impose mandatory discounts for certain patient groups, such as Medicare, Medicaid and Veterans Affairs ("VA") hospitals, and may seek to increase such discounts at any time. Future regulation may negatively impact the price of our product candidates, if approved. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage or reimbursement will be available for any drug candidate that we commercialize and, if coverage or reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any drug candidate for which we obtain marketing approval. In order to get coverage and reimbursement, physicians may need to show that patients have superior treatment outcomes with our products compared to standard of care drugs, including lower-priced generic versions of standard of care drugs. It is possible that a third-party payor may consider our product candidates, once approved, and other therapies as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, once approved, compared to existing products, pricing of existing products may limit the amount we will be able to charge for our product candidates. Third-party payors may deny or revoke the reimbursement status of a given drug product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. Because NOV004 is in the early stages of development, we are unable at this time to determine the likely level or method of coverage and reimbursement from third-party payors. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any drug candidate for which we obtain marketing approval. In the United States, no uniform

policy of coverage and reimbursement for products exists among third-party payors, and coverage decisions and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the medicine is approved by the FDA or other comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but make their determinations independently and may impose additional restrictions. Our inability to promptly obtain and maintain coverage and profitable payment rates from both government-funded and private payors for any approved products we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize drug candidates, and our overall financial condition. Further, coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

In the EU, coverage and reimbursement status of any drug candidates for which we obtain regulatory approval are provided for by the national laws of EU member states. The requirements may differ across the EU member states. Also, at national level, actions have been taken to enact transparency laws regarding payments between pharmaceutical companies and health care professionals.

If we engage in acquisitions, we will incur a variety of costs and we may never realize the anticipated benefits of such acquisitions.

We are presently engaging in a strategy to acquire businesses, technologies or drug candidates that we believe are a strategic fit with our business. If we do undertake any acquisitions, the process of integrating an acquired business, technology or drug candidate into our business may result in unforeseen operating difficulties and expenditures, including diversion of resources and management's attention from our core business. In addition, we may fail to retain key executives and employees of the companies we acquire, which may reduce the value of the acquisition or give rise to additional integration costs. Future acquisitions could result in additional issuances of equity securities that would dilute the ownership of existing stockholders. Future acquisitions could also result in the incurrence of debt, contingent liabilities or the amortization of expenses related to other intangible assets, any of which could adversely affect our operating results. In addition, we may fail to realize the anticipated benefits of any acquisition.

Interim, top-line and preliminary data from our future clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or top-line data from our future clinical studies, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical studies.

In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data from future clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular drug candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based

on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, drug candidate or our business. If the top-line data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our drug candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Changes in funding for the FDA and other government agencies or other disruptions at these agencies could prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA and other agencies to review and approve new drugs can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may prolong the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Even if we obtain regulatory approval for a potential drug candidate, it will remain subject to extensive ongoing regulatory review and requirements.

If any of our future drug candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive requirements imposed by the FDA and comparable foreign regulatory authorities, including ensuring that quality control and manufacturing procedures conform to cGMPs regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for our potential drug candidates will be subject to limitations on the approved indicated uses for which the drug candidate may be marketed and promoted or to the conditions of approval (including the potential for a requirement to implement a Risk Evaluation and Mitigation Strategy) or contain requirements for potentially costly post-marketing testing. We will be required to report certain adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in drug development or commercialization, or increased costs to assure compliance. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of drug candidates to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. We will have to comply with requirements concerning advertising and promotion for our potential drug candidates. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the drug candidate's approved label. As such, we may not promote our potential drug candidates for indications or uses for which they do not have approval. The holder of an approved NDA must submit new or supplemental applications and obtain approval for certain changes to the approved drug candidate labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our potential drug candidates in general or in specific patient subsets. If original marketing approval was obtained via the accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial to confirm clinical benefit for our drug candidates. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a drug or device, such as adverse events of unanticipated severity or frequency, or problems with the facility where the drug candidate is manufactured, or disagrees with the promotion, marketing or labeling of a drug candidate, such regulatory agency may impose restrictions on that drug candidate or us, including

requiring withdrawal of the drug candidate from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning or untitled letters that would result in adverse publicity;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approvals;
- suspend any of our ongoing clinical trials;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us to enter into a consent decree or permanent injunction, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- withdraw regulatory approval;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities;
- seize or detain drug candidates; or
- require a drug candidate recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our drug candidates. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

The policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our potential drug candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any future marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

Non-compliance by us or any future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population can also result in significant financial penalties.

If we fail to comply with healthcare laws, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

Our operations are subject to various federal and state fraud and abuse and other healthcare laws. The laws that may impact our operations include:

- federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- federal civil and criminal false claims laws, including the False Claims Act, and civil monetary penalty laws, which impose criminal and civil penalties, including through civil "qui tam" or "whistleblower" actions, against individuals or entities from, among other things, knowingly presenting, or causing to be presented, claims for payment or

approval from Medicare, Medicaid, or other third-party payors that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation;

- the federal HIPAA, which created new federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates and their subcontractors that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;
- the federal Physician Payment Sunshine Act, created under the ACA, and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services under the Open Payments Program, information related to payments or other transfers of value made to physicians, (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require the registration of sales representatives; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities, including compensating physicians with stock or stock options, could, despite our efforts to comply, be subject to challenge under one or more of such laws. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our drug candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We and any contract manufacturers and suppliers we engage are subject to numerous federal, state, and local environmental, health, and safety laws, regulations, and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment, and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air, and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and radioactive materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, drug development and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our business activities may be subject to the Foreign Corrupt Practices Act ("FCPA") and similar anti-bribery and anti-corruption laws.

Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we may operate, including the U.K. Bribery Act. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently the Securities and Exchange Commission ("SEC") and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our drug candidates in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize potential future drug candidates.

We may consider collaboration arrangements with pharmaceutical or biotechnology companies for the development or commercialization of drug candidates depending on the merits of retaining or divesting some or all commercialization rights. We will face, to the extent that we decide to enter into collaboration agreements, significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time-consuming to negotiate, document, implement and maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we so chose to enter into such arrangements. The terms of any collaborations or other arrangements that we may establish may not be favorable to us.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our drug candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive drug candidates, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, abandon a drug candidate, repeat or conduct new clinical trials or require a new formulation of a drug candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, drug candidates that compete directly or indirectly with our drug candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more drug candidates may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our current or future drug candidates or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future drug candidates;
- collaborators may own or co-own intellectual property covering our drug candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Risks Relating to Our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our current drug candidates, any future drug candidates, and other proprietary technology we develop, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize drug candidates similar or identical to ours, and our ability to successfully commercialize our current drug candidate, if approved, any future drug candidates, and other proprietary technologies if approved, may be adversely affected.*

Our commercial success will depend in part on obtaining and maintaining a combination of patent protection, trade secret protection and confidentiality agreements to protect the intellectual property related to our current and future drug candidates and the methods used to manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our drug candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the United States or in many jurisdictions outside of the United States. Changes in either the patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be enforced in the issued patents that we currently own, or in patents that may issue from the applications we currently or may in the future own or license from third parties. Further, if any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our technology could be adversely affected.

Others may have filed, and in the future are likely to file, patent applications covering drug candidates that are similar, identical or competitive to ours or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed or in-licensed by us, or that we or our licensors will not be involved in interference, opposition or invalidity proceedings before U.S. or non-U.S. patent offices.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our current or future drug candidates and proprietary technologies and erode or negate any competitive advantage we may have, which could have a material adverse effect on our financial condition and results of operations. For example:

- others may be able to make compounds that are similar to our drug candidates but that are not covered by the claims of our patents;
- we might not have been the first to make the inventions covered by our pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- any patents that we obtain may not provide us with any competitive advantages;
- we may not develop additional proprietary technologies that are patentable; or
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they would significantly harm our business, results of operations and prospects.

We have applied, and we intend to continue applying, for patents covering aspects of our current drug candidates, any future drug candidates, or other proprietary technologies and their uses that we deem appropriate. However, we may not be able to apply for patents on certain aspects of our current or future drug candidates, proprietary technologies and their uses in a timely fashion, at a reasonable cost, in all jurisdictions, or at all, and any potential patent coverage we obtain may not be sufficient to prevent substantial competition. As of September 30, 2023, Novosteo LLC, our wholly owned subsidiary, is the owner of record of one pending Patent Cooperation Treaty patent application related to certain uses of NOV004.

Without patent protection on the composition of matter of our current or future drug candidates, our ability to assert our patents to stop others from using or selling our current or future drug candidates may be limited. Due to the patent laws of a country, or the decisions of a patent examiner in a country, or our own filing strategies, we may not obtain patent coverage for all of our current or future drug candidates or methods involving the use of these candidates in a particular patent application. We plan to pursue divisional patent applications or continuation patent applications in the United States and other countries, where applicable, to obtain claim coverage for inventions which were disclosed but not claimed in a particular parent patent application.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our actual or potential future collaborators will be successful in protecting our current drug candidates, any future drug candidate, and other proprietary technologies and their uses by obtaining, defending, and enforcing patents. These risks and uncertainties include the following:

- the U.S. Patent and Trademark Office, or USPTO, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell our potential drug candidates;

- other parties may have designed around our claims or developed technologies that may be related or competitive to our platform, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same compounds, compositions of matter, or methods, or formulations, or by claiming subject matter that could dominate our patent position;
- any successful opposition to any patents owned by or licensed to us could deprive us of rights necessary to prevent others from practicing our technologies or to successfully commercialize any drug candidates that we may develop;
- because patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we or our licensors were the first to file any patent application related to our current drug candidates, any future drug candidates, and other proprietary technologies and their uses;
- an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of applications we may in-license which have an effective filing date before March 16, 2013;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing drug candidates in those countries.

The patent prosecution process is also expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection for such output. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in any of our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. We may also rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or feasible. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

We depend on a license agreement with Purdue and termination of this license could result in the loss of significant rights, which would harm our business.*

On June 3, 2020, Novosteo, Inc. entered into a License Agreement with Purdue Research Foundation, as amended on March 21, 2022, July 22, 2022, and June 22, 2023, which License Agreement was assigned to us on October 17, 2022 (as amended, the “Purdue Agreement”). Under the Purdue Agreement, we obtained an exclusive worldwide license under bone fracture repair therapeutics related patents and technology developed by the Purdue University and owned by Purdue Research Foundation to make or have made, use, sell or have sold, and import, and otherwise exploit products that are covered by such patents and technology, including the right to grant and authorize sublicenses, subject to Purdue Research Foundation’s consent. Such exclusive license is subject to certain rights retained by the U.S. government and Purdue Research Foundation. As of September 30, 2023, we are the exclusive licensee of one issued U.S. patent, one issued non-U.S. patent and at least 35 pending U.S. and non-U.S. patent applications under the Purdue Agreement.

Under the Purdue Agreement, one issued U.S. patent relates to NOV004, with claims directed to NOV004 and related pharmaceutical compounds and use of these compounds in the treatment of bone fractures. Pending U.S. and non-U.S. patent

applications relate to NOV004 and related pharmaceutical compounds, pharmaceutical compositions containing these compounds, and methods of using these compounds in the treatment of various indications.

In addition, we are required to pay Purdue Research Foundation annual license maintenance fee, development milestones (up to $4.25 million for each licensed product), low single digit running royalty on the gross receipts of the licensed products (subject to minimum annual royalty), and a share of certain payments that we may receive from our sublicensees. As a result, it may not be possible for us to develop and manufacture any drug candidates at a cost or in quantities sufficient to make these drugs commercially viable or to maintain current operating margins. The Purdue Agreement also requires us to bear the cost of the prosecution and maintenance of the licensed patents.

Pursuant to the Purdue Agreement, we are required to use commercially reasonable efforts to develop, manufacture and commercialize the licensed product in accordance with a mutually agreed development timelines and commercialization plan.

If we fail to pay any sum due, miss any milestone timelines or otherwise materially breach the agreement or fail to cure such breach within specified cure period), Purdue has the right to terminate our license, and upon the effective date of such termination, we must cease all activities licensed all rights, data, information, know-how, and material licensed or transferred to us under this license agreement will revert to Purdue and all rights, data, information, know-how, material, records and registrations developed or made by us that relate in whole or in part to the activities contemplated by our amended and restated license agreement with Purdue will be transferred to Purdue. Any uncured, material breach under the license agreement could result in loss in our rights to develop and market NOV004 and experience significant delays in the development or commercialization of NOV004, which could have a material adverse impact on our operations and financial condition and results.

Further, Purdue Research Foundation or any future licensors may not always act in our best interest. If disputes over intellectual property rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, our business, results of operations, financial condition, and prospects may be adversely affected. We may enter into additional licenses in the future and if we fail to comply with obligations under those agreements, we could suffer adverse consequences.

In addition, the United States federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act, or the Bayh-Dole Act. Under the Bayh-Dole Act, the federal government retains a “nonexclusive, nontransferable, irrevocable, paid-up license” for its own benefit in invention produced with its financial assistance. The Bayh-Dole Act also provides federal agencies with “march-in rights.” March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a “nonexclusive, partially exclusive, or exclusive license” to a “responsible applicant or applicants.” If the patent owner refuses to do so, the government may grant the license itself. We sometimes collaborate with academic institutions to accelerate our preclinical research or development. While it is our policy to avoid engaging our university partners in projects in which there is a risk that federal funds may be commingled, we cannot be sure that any co-developed intellectual property will be free from government rights pursuant to the Bayh-Dole Act. If, in the future, we co-own or license in technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming, and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged in court, and we may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

Third parties, including competitors, may infringe, misappropriate or otherwise violate our patents, patents that may issue to us in the future, or the patents of our licensors that are licensed to us. To counter infringement or unauthorized use, we may need to choose to file infringement claims, which can be expensive and time-consuming. We may not be able to prevent, alone or with our licensors, infringement, misappropriation, or other violation of our intellectual property, particularly in countries where the laws may not protect those rights as fully as in the United States. If we choose to go to court to stop another party from using the inventions claimed in any patents we obtain, that individual or company has the right to ask the court to rule that such patents are invalid or should not be enforced against that third party for any number of reasons. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements for patentability, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. Similar mechanisms for challenging the validity and enforceability of a patent exist in non-U.S. patent offices and may result in the revocation, cancellation, or amendment of any non-U.S. patents we hold in the future. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and prior art could render our patents, or those of our licensor’s, invalid. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose

at least part, and perhaps all, of the patent protection on one or more drug candidates. Such a loss of patent protection would have a material adverse impact on our business.

These lawsuits are expensive and would consume time and resources and divert the attention of managerial and scientific personnel even if we were successful in stopping the infringement of such patents. In addition, there is a risk that the court will decide that such patents are not valid and that we do not have the right to stop the other party from using the claimed inventions. There is also the risk that, even if the validity of such patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our rights to such patents. In addition, the U.S. Supreme Court has recently modified some tests used by the USPTO in granting patents over the past 20 years, which may decrease the likelihood that we will be able to obtain patents and increase the likelihood of challenge of any patents we obtain or license.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications, or those of our licensor's. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our current and any future drug candidates to market.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their drug candidates. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's drug candidate. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

In addition, proceedings to enforce or defend our patents, including those of our licensor's, could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any of our patents covering our drug candidates are invalidated or found unenforceable, or if a court found that valid, enforceable patents held by third parties covered one or more of our drug candidates, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights. If we initiate lawsuits to protect or enforce our patents, or litigate against third party claims, such proceedings would be expensive and would divert the attention of our management and technical personnel.

We may infringe the intellectual property rights of others, which may prevent or delay our drug development efforts and stop us from commercializing or increase the costs of commercializing our drug candidates.

Our success will depend in part on our ability to operate without infringing the intellectual property rights of third parties. We cannot guarantee that our drug candidates, or manufacture or use of our drug candidates, will not infringe third-party patents.

Furthermore, a third party may claim that we or our manufacturing or commercialization collaborators are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our drug candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and scientific personnel. There is a risk that a court would decide that we or our commercialization collaborators are infringing the third party's patents and would order us or our collaborators to stop the activities covered by the patents. In that event, we or our commercialization collaborators may not have a viable way around the patent and may need to halt

commercialization of the relevant drug candidate. In addition, there is a risk that a court will order us or our collaborators to pay the other party damages for having violated the other party's patents. If we collaborate with third parties in the development of technology in the future, our collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability. Further, our collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability. In the future, we may agree to indemnify our collaborators against certain intellectual property infringement claims brought by third parties. The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of drug candidates or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform.

Any claims of patent infringement asserted by third parties would be time consuming and could:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from out-licensing our legacy assets or commercializing NOV004, or our other drug candidates until the asserted patent expires or is finally held invalid, unenforceable, or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- require us to pay damages to the party whose intellectual property rights we may be found to be infringing, which may include treble damages if we are found to have been willfully infringing such intellectual property;
- require us to pay the attorney's fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing; and/or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all.

If we are sued for patent infringement, we would need to demonstrate that our drug candidates or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity or unenforceability is difficult.

For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, which may not be available, defend an infringement action or challenge the validity or enforceability of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid or unenforceable, we may incur substantial monetary damages, encounter significant delays in bringing our drug candidates to market and be precluded from manufacturing or selling our drug candidates.

We do not routinely conduct independent reviews of pending patent applications of and patents issued to third parties. We cannot be certain that others have not filed patent applications for technology covered by our pending applications, or that we were the first to invent the technology, because:

- some patent applications in the United States may be maintained in secrecy until the patents are issued;
- patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived;
- pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our drug candidates or the use of our drug candidates;
- identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims;

- patent applications in the United States are typically not published until 18 months after the priority date; and
- publications in the scientific literature often lag behind actual discoveries.

Furthermore, the scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history and can involve other factors such as expert opinion. Our interpretation of the relevance or the scope of claims in a patent or a pending application may be incorrect, which may negatively impact our ability to market our drug candidates. Further, we may incorrectly determine that our technologies, or drug candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our drug candidates.

Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours, and others may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our drug candidates and future approved products or impair our competitive position. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing drug candidates. There may be third-party patents or patent applications with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our drug candidates. Any such patent application may have priority over our patent applications, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar inventions prior to our own inventions, resulting in a loss of our U.S. patent position with respect to such inventions. Other countries have similar laws that permit secrecy of patent applications, and may be entitled to priority over our applications in such jurisdictions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. There can be no assurance that our operations do not, or will not in the future, infringe existing or future third-party patents. Identification of third-party patent rights that may be relevant to our operations is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

Numerous U.S. and foreign patents and pending patent applications exist in our market that are owned by third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our products. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. applications that will not be filed outside the U.S. can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our products or the use of our products. As such, there may be applications of others now pending or recently revived patents of which we are unaware. These patent applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our products.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a

third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, including our research programs, product candidates, their respective methods of use, manufacture and formulations thereof, and could result in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on any issued patents and/or pending applications are due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm to pay these fees due to the USPTO and non-U.S. patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. If we license intellectual property, we may have to rely upon our licensors to comply with these requirements and effect payment of these fees with respect to any patents and patent applications that we license. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers. If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and drug candidate could be significantly diminished.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. We may also be subject to claims that former employees, or other third parties have an ownership interest in our patents or other intellectual property. In addition, we may face claims by third parties that our agreements with employees, contractors or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, and invention assignment agreements with employees, consultants and advisors, to protect our trade secrets and other proprietary information. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Despite these efforts, we cannot provide any assurances that all such agreements have been duly executed, and these agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or

other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

In addition, such security measures may not provide adequate protection for our proprietary information, for example, in the case of misappropriation of a trade secret by an employee, consultant, customer or third party with authorized access. Our security measures may not prevent an employee, consultant or customer from misappropriating our trade secrets and providing them to a competitor, and any recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our drug candidates that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, the criteria for protection of trade secrets can vary among different jurisdictions.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. Trade secrets could over time be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel skilled in the art from company to company or academic to industry scientific positions.

Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors and consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Because from time to time we expect to rely on third parties in the development, manufacture, and distribution of our drug candidates and provision of our services, we must, at times, share trade secrets with them. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position would be harmed.

In the future, we may need to obtain licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms, and which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.

From time to time we may be required to license technology from third parties to further develop or commercialize our drug candidates. Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use or sell our drug candidates, such licenses may not be available to us on commercially reasonable terms, or at all. The inability to obtain any third-party license required to develop or commercialize any of our drug candidates could cause us to abandon any related efforts, which could seriously harm our business and operations.

Where we obtain licenses from or collaborate with third parties, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties, or such activities, if controlled by us, may require the input of such third parties. We may also require the cooperation of our licensors and collaborators to enforce any licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business, in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. Moreover, if we do obtain necessary licenses, we will likely have obligations under those licenses, including making royalty and milestone payments, and any failure to satisfy those obligations could give our licensor the right to terminate the license.

Termination of a necessary license, or expiration of licensed patents or patent applications, could have a material adverse impact on our business. Our business would suffer if any such licenses terminate, if the licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Furthermore, if any exclusive licenses terminate, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties may gain the freedom to seek regulatory approval of, and to market, drug candidates identical to ours. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are

infringing or otherwise violating the licensor's rights. In addition, while we cannot currently determine the amount of the royalty obligations, we would be required to pay on sales of future drug candidates, if any, the amounts may be significant. The amount of our future royalty obligations will likely depend on the technology and intellectual property we use in drug candidates that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize drug candidates, we may be unable to achieve or maintain profitability.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make drug candidates that are similar to ours but that are not covered by the claims of the patents that we own;
- we or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive drug candidates for sale in our major commercial markets;
- we cannot ensure that any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our drug candidates;
- we cannot ensure that any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable drug candidates or will provide us with any competitive advantages;
- we cannot ensure that our commercial activities or drug candidates will not infringe upon the patents of others;
- we cannot ensure that we will be able to successfully commercialize our drug candidates on a substantial scale, if approved, before the relevant patents that we own or license expire;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications;

Should any of these events occur, they would significantly harm our business, results of operations and prospects.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.*

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. Our competitors or other third parties may be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in-license needed technology or other product candidates, or enter into development partnerships that would help us bring our product candidates to market. In such cases, we may

decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

We may not be able to protect our intellectual property rights throughout the world.*

Patents are of national or regional effect, and filing, prosecuting and defending patents on all of our drug candidates throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. As such, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing drug candidates made using our inventions in and into the United States or other jurisdictions. Further, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing drug candidates in violation of our proprietary rights generally. In addition, certain developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit, and in those countries, we and our licensors and licensees may have limited remedies if patents are infringed or if we or our licensors or licensees are compelled to grant a license to a third party, which could diminish the value of those patents. This could limit our potential revenue opportunities. Further, competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drug candidates and, further, may export otherwise infringing drug candidates to territories where we have patent protection but where enforcement is not as strong as that in the United States. These drug candidates may compete with our drug candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

In Europe, beginning June 1, 2023, European applications and patent may be subjected to the jurisdiction of the Unified Patent Court (the "UPC"). Also, European applications will have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the UPC. This will be a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty. As a single court system can invalidate a European patent, we, where applicable may opt out of the UPC and as such, each European patent would need to be challenged in each individual country.

Geo-political actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, the United States and foreign government actions related to Russia’s invasion of Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees that have citizenship or nationality in, are registered in, or have predominately primary place of business or profit-making activities in the United States and other countries that Russia has deemed unfriendly without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our drug candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Our patent rights may be affected by developments or uncertainty in U.S. or non-U.S. patent statutes, patent case laws in USPTO rules and regulations or in the rules and regulations of non-U.S. patent offices.

Obtaining and enforcing patents in the pharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs. Recent patent reform legislation in the United States and other countries,

including the Leahy-Smith America Invents Act (the Leahy-Smith Act), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter parties review, and derivation proceedings. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, Congress may pass patent reform legislation that is unfavorable to us.

The U.S. Supreme Court has ruled on several patent cases in recent years, narrowing the scope of patent protection available in certain circumstances and weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents, trade secrets or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our drug candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

In addition, we may be unsuccessful in executing agreements assigning such intellectual property to us with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Patent terms may be inadequate to protect our competitive position on our drug candidates for an adequate amount of time, and if we do not obtain patent term extension for our drug candidates, our business may be materially harmed.

Patent rights are of limited duration. In the United States, the natural expiration of a patent is generally 20 years after its first effective non-provisional filing date. In addition, although upon issuance a U.S. patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such drug candidates are commercialized. Even if patents covering our drug candidates are obtained, once the patent life has expired for a drug candidate, we may be open to competition from generic products. A patent term extension of up to five years based on regulatory delay may be available in the United States under the Hatch- Waxman Act. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single drug candidate. Moreover, the scope of protection during the period of the patent term extension does not extend to the full

scope of the claim, but instead only to the scope of the drug candidate as approved. Further, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug candidate approval and only those claims covering such approved drug candidate, a method for using it or a method for manufacturing it may be extended. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our drug candidate will be shortened and our competitors may obtain approval of competing drug candidates following our patent expiration, and our revenue could be reduced.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

Moreover, any name we have proposed to use with our drug candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed drug candidate names, including an evaluation of potential for confusion with other drug candidate names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary drug candidate names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue or that patents based on our patent applications will not be challenged and rendered invalid and/or unenforceable.*

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. We have pending U.S. and foreign patent applications in our portfolio; however, we cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications;

- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries; and/or
- whether we may experience patent office interruption or delays to our ability to timely secure patent coverage to our product candidates.

We cannot be certain that the claims in our pending patent applications directed to our product candidates and/or technologies will be considered patentable by the USPTO or by patent offices in foreign countries. There can be no assurance that any such patent applications will issue as granted patents. One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Even if the patents do issue based on our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our product candidates. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.*

Because our development programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our product candidates, there may be times when the filing and prosecution activities for patents and patent applications relating to our product candidates are controlled by our future licensors or collaboration partners. If any of our future licensors or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our future licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

We may enter into license agreements in the future with others to advance our existing or future research or allow commercialization of our existing or future product candidates. These licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future.

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technology that we license from third parties. In such an event, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our future licensors fail to

prosecute, maintain, enforce, and defend such patents or patent applications, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our future product candidates that are subject of such licensed rights could be adversely affected.

Our future licensors may rely on third-party consultants or collaborators or on funds from third parties such that our future licensors are not the sole and exclusive owners of the patents we in-license. If other third parties have ownership rights to our future in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

It is possible that we may be unable to obtain licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

Disputes may arise between us and our future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we license in the future prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

In spite of our best efforts, our future licensors might conclude that we materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

From time to time, we may be required to license technologies relating to our therapeutic research programs from additional third parties to further develop or commercialize our product candidates. Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use or sell our product candidates, such licenses may not be available to us on commercially reasonable terms, or at all. The inability to obtain any third-party license required to develop or commercialize any of our product candidates could cause us to abandon any related efforts, which could seriously harm our business and operations.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our products or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our future product candidates or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable future product candidates;
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Risks Relating to Owning Our Common Stock

The market price of our common stock is likely to be volatile and could fluctuate or decline, resulting in a substantial loss of your investment.

The market price of our common stock has been and may continue to be volatile and could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including:

- the outcome of our review and evaluation of strategic alternatives;
- changes in our business strategy;
- results of clinical trials;
- our ability to identify partnership and licensing opportunities to support the future development of NOV004;
- our ability to in-license or acquire clinical stage therapeutics
- any delays in manufacturing of drug supplies, results of preclinical studies and clinical trials for potential drug candidates;
- regulatory actions with respect to our potential drug candidates or our competitors' drug candidates;
- actual or anticipated fluctuations in our financial condition and operating results, including fluctuations in our quarterly and annual results;
- announcement of actual or anticipated reduction in force, including our recent reduction in force;
- announcements of technological innovations by us or our competitors;
- overall conditions in our industry and the markets in which we operate;
- addition or loss of significant customers, or other developments with respect to significant customers;

- changes in laws or regulations applicable to our drug candidates;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- additions or departures of key personnel;
- competition from existing drug candidates or new drug candidates that may emerge;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain intellectual property protection for our technologies;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us or our stockholders;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- market conditions for pharmaceutical stocks in general;
- the expiration of contractual lock-up agreements with our executive officers, directors and stockholders;
- general economic and market conditions; and
- ineffectiveness of our disclosure controls or internal controls.

Furthermore, the stock markets have experienced price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations often have been unrelated or disproportionate to the operating performance of those companies. These broad market and industry fluctuations, as well as general economic, political and market conditions such as recessions, interest rate changes or international currency fluctuations, may negatively impact the market price of our common stock. In the past, stockholders have instituted securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

We may be subject to securities class action and stockholder derivative actions. These, and potential similar or related litigation, could result in substantial damages and may divert management's time and attention from our business and adversely impact our business, results of operations and financial condition.

We may become the target of securities class actions or stockholder derivative claims. Securities-related class action litigation has often been brought against companies, including many biotechnology companies, which experience volatility in the market price of their securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies often experience significant stock price volatility in connection with their product development programs. Any preclinical or clinical trial results that the investors may deem as unfavorable, volatility in our stock price and other matters affecting our business and operations may subject us to actual and threatened securities class actions or stockholder derivative claims. In addition, we may be exposed to increased litigation from stockholders, customers, suppliers, consumers and other third parties due to the combination of Novosteo's business and ours following the Novosteo Acquisition, out-licensing of our legacy assets or any potential strategic transactions. These types of proceedings may result in substantial costs, divert management's attention from other business concerns and adversely impact our business, results of operations and financial condition.

Future sales of our common stock in the public market could cause our share price to fall.

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. Certain holders of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in Securities Act registration statements that we may file for ourselves or other stockholders. Once we register these shares, they can be freely sold in the public market. Moreover, we have also registered under the Securities Act shares of common stock that we may issue under our equity compensation plans.

In addition, the issuance of shares under awards granted under existing or future employee equity benefit plans may cause immediate and substantial dilution to our existing stockholders. In the future, we may issue additional shares of common stock or other equity or debt securities convertible into common stock in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause our stock price to decline.

We have in the past and may in the future fail to continue to meet the listing standards of Nasdaq, and as a result our common stock may be delisted, which could have a material adverse effect on the liquidity of our common stock.*

Our common stock currently trades on The Nasdaq Global Select Market. The Nasdaq Stock Market LLC ("Nasdaq") has requirements that a company must meet in order to remain listed on Nasdaq. For example, Nasdaq rules require us to maintain a minimum closing bid price of $1.00 per share of our common stock.

On December 13, 2022, we received a letter from the Listing Qualifications Staff, or the "Nasdaq Staff" of Nasdaq notifying us that for the last 30 consecutive business days, the bid price of our common stock had closed below $1.00 per share, the minimum closing bid price required by the continued listing requirements of Nasdaq Listing Rule 5450(a)(1). The notification received had no immediate effect on the listing of our common stock on the Nasdaq Global Select Market. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we had 180 calendar days to regain compliance with the minimum bid price requirement by having shares of our common stock maintain a minimum closing bid price of at least $1.00 per share for a minimum of 10 consecutive trading days. On April 4, 2023, we received a letter from the Nasdaq Staff notifying us that the closing bid price of our common stock had been at $1.00 per share or greater for 10 consecutive business days, from March 21, 2023 to April 3, 2023, and accordingly, we had regained compliance with Nasdaq Listing Rule 5450(a)(1). There can be no assurance that we will continue to meet the minimum bid price requirement, or any other Nasdaq requirements, in the future.

The closing price of our common stock has been below $1.00 per share for twelve consecutive business days since October 27, 2023. If the bid price of our common stock closes below $1.00 for 30 consecutive business days, we will no longer be in compliance with the Nasdaq minimum bid price requirement.

In addition, we may be unable to meet other applicable Nasdaq listing requirements, including maintaining minimum levels of stockholders' equity or market values of our common stock, in which case our common stock could be delisted. If our common stock were to be delisted, the liquidity of our common stock would be adversely affected, and the market price of our common stock could decrease.

We have never paid dividends on our common stock and we do not intend to pay dividends for the foreseeable future. Consequently, any gains from an investment in our common stock will likely depend on whether the price of our common stock increases.

We have never declared or paid any dividends on our common stock and do not intend to pay any dividends in the foreseeable future. We anticipate that we will retain all of our future earnings for use in the operation of our business and for general corporate purposes. Any determination to pay dividends in the future will be at the discretion of our board of directors. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments.

General Risk Factors

Our charter documents and Delaware law could prevent a takeover that stockholders consider favorable and could also reduce the market price of our stock.*

Our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions could also make it more difficult for stockholders to elect directors and take other corporate actions. These provisions include:

- providing for a classified board of directors with staggered, three-year terms;
- authorizing our board of directors to issue preferred stock with voting or other rights or preferences that could discourage a takeover attempt or delay changes in control;
- prohibiting cumulative voting in the election of directors;

- providing that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- prohibiting the adoption, amendment or repeal of our amended and restated bylaws or the repeal of the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors without the required approval of at least 66.67% of the shares entitled to vote at an election of directors;
- prohibiting stockholder action by written consent;
- limiting the persons who may call special meetings of stockholders; and
- requiring advance notification of stockholder nominations and proposals.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, the provisions of Section 203 of the Delaware General Corporate Law, or the DGCL, govern us. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time without the consent of our board of directors.

In addition, in April 2023, we implemented the Rights Agreement, also called a "poison pill," that may have the effect of discouraging or preventing a change of control by, among other things, making it uneconomical for a third party to acquire us without the consent of our board of directors.

These and other provisions in our amended and restated certificate of incorporation and our amended and restated bylaws and under Delaware law could discourage potential takeover attempts, reduce the price investors might be willing to pay in the future for shares of our common stock and result in the market price of our common stock being lower than it would be without these provisions.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' abilities to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that, unless we consent to the selection of an alternative forum, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by, or other wrongdoing by, any of our directors, officers, employees or agents or our stockholders;
- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation, or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine;

provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our amended and restated certificate of incorporation also provides that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action against us or any of our directors, officers, employees or agents and arising under the Securities Act.

We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, these provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees. While the Delaware Supreme Court recently determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring such a claim arising under the Securities Act against us, our directors, officers, or other employees in a venue other than in the federal district courts of the United States of America. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation, and this may require significant additional costs associated with resolving such action in other jurisdictions.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the DGCL, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful;
- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;
- we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;
- we will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification;
- the rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and
- we may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

Our internal computer systems, or those used by our third-party research institution collaborators, CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our future CROs and other contractors and consultants may be vulnerable to damage from computer viruses and unauthorized access. Although to our knowledge we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on our third-party research institution collaborators for research and development of our drug candidates and other third parties for the manufacture of our drug candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our drug candidates could be delayed.

Our ability to utilize our federal net operating loss and tax credit carryforwards may be limited.

Our net operating loss, or NOL, carryforwards could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. NOLs generated in tax years ending on or prior to December 31, 2017 are only permitted to be carried forward for 20 taxable years under applicable U.S. federal tax law. Moreover, under the Tax Act as modified by the CARES Act, federal NOLs generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs may be limited to 80% of taxable income for tax years beginning January 1, 2018.

Under Sections 382 and 383 of the Internal Revenue Code, limitations on a corporation's ability to use its NOLs and tax credit carryforwards apply if a corporation undergoes an "ownership change," which is generally defined as a greater than 50

percentage point change (by value) in its equity ownership by certain stockholders over a three-year period. If we have experienced an ownership change at any time since our incorporation, we may already be subject to limitations on our ability to utilize our existing NOL carryforwards and other tax attributes to offset taxable income or tax liability. In addition, future changes in our stock ownership, which may be outside of our control, may trigger an ownership change. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. As a result, even if we earn net taxable income in the future, our ability to use our pre-change NOL carryforwards and other tax attributes to offset such taxable income or tax liability may be subject to limitations, which could potentially result in increased future income tax liability to us.

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds, and Issuer Purchases of Equity Securities.

None.

Item 3. Defaults Upon Senior Securities.

Not Applicable.

Item 4. Mine Safety Disclosures.

Not Applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

The exhibits filed or furnished as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, timely and successful completion which Exhibit Index is incorporated herein by reference.

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
2.1*	Stock Purchase Agreement, dated as of July 21, 2023 by and among Quince Therapeutics, Inc., EryDel Italy, Inc., EryDel S.p.A., certain holders and managers set forth on Schedule II thereto, and Shareholder Representative Services LLC, as the stockholder representative	8-K	7/24/2023	001-38890	
3.1	Amended and Restated Certificate of Incorporation	8-K	5/13/2019	001-38890	
3.2	Certificate of Amendment to the registrant's Certificate of Incorporation, effective August 1, 2022	8-K	8/1/2022	001-38890	
3.3	Amended and Restated Bylaws	8-K	8/1/2022	001-38890	
3.4	Certificate of Designation of Series A Junior Participating Preferred Stock	8-K	4/5/2023	001-38890	
4.1	Rights Agreement dated as of April 5, 2023, between Quince Therapeutics, Inc. and American Stock Transfer & Trust Company, LLC	8-K	4/5/2023	001-38890	
10.1**	Amendment No. 3 to License Agreement dated June 22, 2023 by and between Purdue Research Foundation and Novosteo Inc.	10-Q	8/3/2023	001-38890	
10.2	Transition and Separation Agreement between Quince Therapeutics, Inc. and Karen Smith, dated as of August 4, 2023				X
10.3	Offer Letter between Quince Therapeutics, Inc. and Charles Ryan, dated as of August 1, 2023				X
10.4	Executive Change in Control and Severance Agreement between Quince Therapeutics, Inc. and Charles Ryan, dated as of September 1, 2023				X
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and Rule 15d-14(a) of the Exchange Act				X
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and Rule 15d-14(a) of the Exchange Act				X
32.1#	Certification of Principal Executive Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X
32.2#	Certification of Principal Financial Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X
101.INS	Inline XBRL Instance Document				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				X
104	Cover Page Interactive Data File, formatted in Inline XBRL (included in Exhibit 101)				

* Certain exhibits and schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The registrant agrees to furnish supplementally to the SEC a copy of any omitted exhibits or schedules upon request.

** Portions of this exhibit have been redacted pursuant to Item 601(b)(10) of Regulation S-K as the Registrant has determined that (i) the omitted information is not material and (ii) the omitted material is of the type that the Registrant treats as private or confidential.

In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release Nos. 33-8238 and 34-47986, Final Rule: Management's Reports on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Quarterly Report on Form 10-Q and will not be deemed "filed" for purpose of Section 18 of the Exchange Act. Such certifications will not be deemed to be incorporated by reference

into any filing under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Quince Therapeutics, Inc.

Date: November 14, 2023

By: /s/ Dirk Thye
Dirk Thye
Chief Executive Officer
(Principal Executive Officer)

Date: November 14, 2023

By: /s/ Brendan Hannah
Brendan Hannah
Chief Business Officer and Chief Operating Officer
(Principal Financial Officer)

QUINCE THERAPEUTICS, INC.

July 21, 2023

Karen Smith
Via Electronic Delivery

Dear Karen:

This letter sets forth the substance of the transition and separation agreement (the "**Agreement**") that Novosteo, Inc. ("**Novosteo**") and Quince Therapeutics, Inc. ("**Quince**," and together with Novosteo, and each individually, as the context requires, the "**Company**") is offering to you to aid in your employment transition.

1.Separation. If you sign this Agreement and allow it to become effective, your employment will continue until September 1, 2023 (the "**Planned Termination Date**") or such earlier date your employment may be terminated pursuant to Section 2(c) below. (Your last day of employment, whenever it occurs, shall be the "**Separation Date**.")

2. Transition Period.

(a) **Duties.** Between now and the Separation Date (the "**Transition Period**"), you will remain an employee of the Company, will be expected to transition your duties and responsibilities to Company personnel and perform other duties and tasks as requested by the Company. During the Transition Period, you must continue to comply with all of the Company's policies and procedures and with all of your statutory and contractual obligations to the Company (including, without limitation, your obligations under this Agreement and your Confidentiality Agreement, defined below). During the Transition Period, you agree to exercise the highest degree of professionalism and utilize your expertise and creative talents in performing your job duties.

(b) **Compensation/Benefits.** During the Transition Period, you will continue to be paid at the same base salary rate, and you will continue to be eligible for the Company's standard benefits, subject to the terms and conditions applicable to such plans and programs. In addition, your Company stock options or other equity awards will continue to vest under the existing terms and conditions set forth in the governing plan documents and option agreement. You will not be able to participate in any bonus, commissions, or incentive program, and will only be eligible to receive the cash compensation expressly set forth herein.

(c) **Termination.** As part of this Agreement, the Company agrees that it will not terminate your employment other than for Cause (as defined herein) before the Planned Termination Date. If prior to the Planned Termination Date, the Company terminates your employment for Cause, or you resign your employment, or your employment ends due to your death or Disability (as defined herein), then you will not be entitled to any further compensation or benefits (including, without limitation, the severance benefits set forth below). For purposes of this Agreement, "**Cause**" for termination will be any one or more of the following: (i) the indictment of or plea of guilty or no contest by you to any felony involving dishonesty; (ii) participation in any fraud against the Company; (iii) material breach of your contractual duties to the Company (including any material violation of any provision or obligation under this Agreement or the Confidentiality Agreement); or (iv) your willful misconduct or other willful violation of Company policy that causes or could reasonably cause material

harm to the Company. For purposes of this Agreement, "**Disability**" means total and permanent disability as defined in Section 22(e)(3) of the Internal Revenue Code of 1986, as amended.

3.Final Pay. On or shortly after the Separation Date, the Company will pay you all accrued salary and all accrued and unused paid time off earned, if any, through the Separation Date, subject to standard payroll deductions and withholdings. You are entitled to this payment regardless of whether or not you sign this Agreement.

4.Severance Benefits. If (i) you timely sign, date and return this fully executed Agreement to the Company, allow it to become effective, and comply with your obligations under it; (ii) your employment with the Company is not terminated for Cause, due to your death or Disability, or as a result of your resignation before the Planned Termination Date; and (iii) on or within twenty-one (21) days after the Separation Date, you execute and return to the Company the Separation Date Release attached hereto as ***Exhibit A*** (the "**Release**"), and allow the releases contained in the Release to become effective and irrevocable (collectively, the "**Severance Preconditions**"), then the Company will deem your employment termination to be a termination without Cause outside of the Change in Control Period pursuant to that certain Executive Change in Control and Severance Agreement between you and the Company, signed by you on May 9, 2022 (the "**Severance Agreement**"), and accordingly, you will receive the following severance benefits from the Company:

(a) You will receive the equivalent of twelve (12) months of your base salary in effect as of the Separation Date, subject to standard payroll deductions and withholdings (the "**Base Salary Severance**"). This amount will be paid in accordance with the Company's normal payroll practices on the Company's regularly scheduled payroll dates commencing with the first regularly scheduled payroll date that occurs at least eight (8) days following the Release Effective Date (as defined in the Release), with the first payment being equal to the number of business days between the Separation Date and the date of the first payment multiplied by your daily base salary rate. You hereby request and authorize the Company to pay you this severance payment by direct deposit to the account specified by you during your employment.

(b) You will receive an additional cash severance payment in an amount equal to one hundred percent (100%) of your target annual bonus opportunity for the year in which the Separation Date occurs, but prorated to the effective date of termination (the "**Target Annual Bonus Severance**"). The Target Annual Bonus Severance payment shall be paid you, subject to all applicable taxes and required withholdings, in a single lump-sum within thirty (30) days following the Separation Date, but no earlier than the Release Effective Date.

(c) You will receive a benefits severance payment in an amount equal to twelve (12) months' of the monthly premiums that would be due for continuation coverage under Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("**COBRA**"), if you were to elect COBRA continuation coverage for you and your eligible dependents (based on the coverage levels in effect immediately prior to the Separation Date and based on the premium amount that would be due for the first month of COBRA coverage if you were to elect such COBRA continuation coverage) (the "**Benefits Severance Payment**"). The Benefits Severance Payment shall be paid to you in a single lump-sum within thirty (30) days following the Release Effective Date and will be made, subject to all applicable taxes and required withholdings, and regardless of whether you elect COBRA continuation coverage.

(d) You shall vest in any outstanding awards relating to the Company's common stock (whether stock options, stock appreciation rights, shares of restricted stock, restricted stock units, performance shares, performance units or other similar awards) (the "**Equity Awards**") that are unvested as of the Separation Date as follows: in the case of any outstanding Equity Awards that are subject to time-based vesting, fifty percent (50%) of any outstanding Equity Awards, and in the case of any outstanding Equity Awards that are subject to performance-based vesting, all performance goals and other vesting criteria generally will be deemed achieved at fifty percent (50%) of target levels as of the Separation Date. The Equity Awards will otherwise remain subject to the terms and conditions of the applicable Equity Award agreement, applicable plan documents, and other equity award documents.

5.Health Insurance. Your participation in the Company's group health insurance plan will end on the last day of the month in which the Separation Date occurs. To the extent provided by the federal COBRA law or, if applicable, state insurance laws, and by the Company's current group health insurance policies, you may be eligible to continue your group health insurance benefits at your own expense following the Separation Date. Later, you may be able to convert to an individual policy through the provider of the Company's health insurance, if you wish. You will be provided with a separate notice describing your rights and obligations under COBRA and a form for electing COBRA coverage.

6.Equity Awards. Under the terms of your Equity Award agreement and the applicable plan documents, vesting of any Equity Awards will cease as of the Separation Date.

7.Eligibility for CIC Severance Benefits. You will be eligible for increased severance benefits (the "**CIC Severance Benefits**") in the event that the Company experiences a Change in Control (as defined in the Severance Agreement) within three (3) months after the Planned Separation Date (the "**Change in Control Period**"). Specifically, subject to satisfaction of the Severance Preconditions, in the event that the Company experiences a Change in Control during the Change in Control Period, then:
(a) the Base Salary Severance set forth in Section 4(a) above will increase from twelve (12) months to eighteen (18) months of your base salary and shall be paid to you in a single lump-sum within thirty (30) days following the effective date of the Change in Control (but no earlier than the Release Effective Date); (b) the Target Annual Bonus Severance set forth in Section 4(b) above will increase from one hundred percent (100%) of your target annual bonus opportunity to one hundred fifty percent (150%) of your target annual bonus opportunity for the year in which the Separation Date occurs, but prorated to the effective date of termination; (c) the Benefits Severance Payment set forth in Section 4(c) above will increase from twelve (12) months to eighteen (18) months; and (d) you shall vest in any outstanding Equity Awards that are unvested as of the Separation Date as follows: in the case of any outstanding Equity Awards that are subject to time-based vesting, one hundred percent (100%) of any outstanding Equity Awards, and in the case of any outstanding Equity Awards that are subject to performance-based vesting, all performance goals and other vesting criteria generally will be deemed achieved at one hundred percent (100%) of target levels (the "**Vesting Acceleration**") as of the effective date of the Change in Control. The Equity Awards will otherwise remain subject to the terms and conditions of the applicable Equity Award agreement, applicable plan documents, and other equity award documents. Notwithstanding anything stated herein or elsewhere to the contrary, if the successor to the Company or any affiliate of such successor does not agree to assume, substitute or otherwise continue any then outstanding Equity Awards at the time of a Change in Control, you shall receive the Vesting Acceleration as of immediately prior to and contingent upon the Change in Control. In the event that you become eligible for the CIC Severance Benefits after the severance benefits set forth in Section 4 have already been paid to you, then the Company will pay you the difference between the CIC Severance Benefits and

the severance benefits previously paid to you, within fifteen (15) business days after the effective date of the Change in Control. For the avoidance of doubt, under no circumstances will you be eligible for the full severance benefits set forth in Sections 4 and the CIC Severance Benefits.

8.No Other Compensation or Benefits. You acknowledge and agree that the benefits offered to you herein fulfill and exceed all of the Company's obligations to pay you any severance benefits in connection with your employment termination, pursuant to your Severance Agreement and any other agreement, plan or policy. By executing this Agreement, you further agree and acknowledge that the Company's obligations to provide you any and all severance benefits, other than as set forth in this Agreement, are hereby extinguished. You further acknowledge that, except as expressly provided in this Agreement, you have not earned, will not earn by the Separation Date, and will not receive from the Company any additional compensation (including base salary, bonus, incentive compensation, or equity), severance, or benefits before or after the Separation Date, with the exception of any vested right you may have under the express terms of a written ERISA-qualified benefit plan (e.g., 401(k) account) or any vested stock options.

9.Expense Reimbursements. You agree that, within ten (10) calendar days after the Separation Date, you will submit your final documented expense reimbursement statement reflecting all business expenses you incurred through the Separation Date, if any, for which you seek reimbursement. The Company will reimburse you for these expenses pursuant to its regular business practice.

10.Return of Company Property. Within five (5) calendar days after the Separation Date (or earlier if requested by the Company), you will return to the Company all Company documents (and all copies thereof) and other Company property in your possession or control, including, but not limited to, Company files, notes, drawings, records, plans, forecasts, reports, studies, analyses, proposals, agreements, drafts, financial and operational information, password and account information, research and development information, sales and marketing information, customer lists, prospect information, pipeline reports, sales reports, personnel information, specifications, code, software, databases, computer- recorded information, tangible property and equipment (including, but not limited to, your Company- provided laptop, computing and electronic devices, mobile telephones, servers), credit cards, entry cards, identification badges and keys; and any materials of any kind which contain or embody any proprietary or confidential information of the Company (and all reproductions or embodiment thereof in whole or in part). You agree that you will make a diligent search to locate any such documents, property and information by the close of business on the Separation Date or as soon as possible thereafter. If you have used any personally owned computer or other electronic device, server, or e-mail system to receive, store, review, prepare or transmit any Company confidential or proprietary data, materials or information, within five (5) calendar days after the Separation Date (or earlier if requested by the Company), you shall provide the Company with a computer-usable copy of such information and then permanently delete and expunge such Company confidential or proprietary information from those systems; and you agree to provide the Company access to your system as requested to verify that the necessary copying and/or deletion is completed. **Your timely compliance with this paragraph is a condition to your receipt of the severance benefits provided under this Agreement.**

11.Proprietary Information Obligations. You acknowledge and reaffirm your continuing obligations under your Confidential Information and Invention Assignment Agreement, a copy of which is attached hereto as ***Exhibit B***.

12.Confidentiality. The provisions of this Agreement will be held in strictest confidence by you and will not be publicized or disclosed by you in any manner whatsoever; *provided, however,* that:
(a) you may disclose this Agreement in confidence to your immediate family and to your attorneys, accountants, tax preparers and financial advisors; (b) you may disclose this Agreement insofar as such disclosure may be necessary to enforce its terms or as otherwise required by law; and (c) you may make statements and disclosures as permitted under the section of this Agreement entitled "Protected Rights." In particular, and without limitation, you agree not to disclose the terms of this Agreement to any current or former Company employee or independent contractor.

13.Non-disparagement. You agree not to disparage the Company, its officers, directors, employees, shareholders, parents, subsidiaries, affiliates, and agents, in any manner likely to be harmful to its or their business, business reputation, or personal reputation. Notwithstanding the foregoing in this paragraph, you may respond accurately and fully to any request for information if required by legal process or in connection with a government investigation. In addition, nothing in this provision or this Agreement is intended to prohibit or restrain you in any manner from making disclosures protected under the whistleblower provisions of federal or state law or regulation or other applicable law or regulation, or from making statements and disclosures as set forth in the section of this Agreement entitled "Protected Rights." You acknowledge and agree that the nondisparagement obligation in this section is not provided in exchange for a raise, bonus or as a condition of continued employment, but rather in exchange for the materially modified terms of employment during the Transition Period, eligibility for severance benefits you were not otherwise eligible to receive, and other consideration provided by the Company in this Agreement.

14.No Voluntary Adverse Action. You agree that you will not voluntarily (except in response to legal compulsion or as permitted under the "Protected Rights" section below) assist any person in bringing or pursuing any proposed or pending litigation, arbitration, administrative claim or other formal proceeding against the Company, its parent or subsidiary entities, affiliates, officers, directors, employees or agents.

15.Cooperation. You agree to cooperate fully with the Company in connection with its actual or contemplated defense, prosecution, or investigation of any claims or demands by or against third parties, or other matters arising from events, acts, or failures to act that occurred during the period of your employment by the Company. Such cooperation includes, without limitation, making yourself available to the Company upon reasonable notice, without subpoena, to provide complete, truthful and accurate information in witness interviews, depositions, and trial testimony. The Company will reimburse you for reasonable out-of-pocket expenses you incur in connection with any such cooperation (excluding foregone wages) and will make reasonable efforts to accommodate your scheduling needs.

16.No Admissions. You understand and agree that the promises and payments in consideration of this Agreement shall not be construed to be an admission of any liability or obligation by the Company to you or to any other person, and that the Company makes no such admission.

17.Release of Claims. In exchange for the consideration provided to you under this Agreement to which you would not otherwise be entitled, you hereby generally and completely release the Company, and its affiliated, related, parent and subsidiary entities, and its and their current and former directors, officers, employees, shareholders, partners, agents, attorneys, predecessors, successors, insurers, affiliates, and assigns from any and all claims, liabilities, demands, causes of action, and obligations, both known and unknown, arising from or in any way related to events, acts, conduct, or omissions occurring

at any time prior to and including the date you sign this Agreement. This general release includes, but is not limited to: (a) all claims arising from or in any way related to your employment with the Company or the decision to terminate that employment; (b) all claims related to your compensation or benefits from the Company, including salary, bonuses, commissions, vacation pay, expense reimbursements, severance pay, fringe benefits, stock, stock options, or any other ownership, equity, or profits interests in the Company; (c) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (d) all tort claims, including claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (e) all federal, state, and local statutory claims, including claims for discrimination, harassment, retaliation, attorneys' fees, or other claims arising under the federal Civil Rights Act of 1964 (as amended), the federal Americans with Disabilities Act of 1990, the federal Age Discrimination in Employment Act (the "**ADEA**"), the Colorado Anti-discrimination Act, the Colorado Minimum Wage Order, the Colorado Labor Relations Act, the California Labor Code (as amended), the California Family Rights Act and the California Fair Employment and Housing Act (as amended). Notwithstanding the foregoing, you are not releasing the Company hereby from: (i) any obligation to indemnify you pursuant to the Articles and Bylaws of the Company, any valid fully executed indemnification agreement with the Company, or applicable law; (ii) any rights you have to file or pursue a claim for workers' compensation or unemployment insurance; (iii) any claims that cannot be waived by law; or (iv) any claims for breach of this Agreement.

18.Release Acknowledgments. You acknowledge that you have been advised that you have a right to consult an attorney regarding this Agreement and that you were given a reasonable time period of not less than twenty-one (21) days in which to do so. You further acknowledge and agree that, in the event you sign this Agreement prior to the end of the reasonable time period, your decision to accept such shortening of time is knowing and voluntary and is not induced by the Company through fraud, misrepresentation, or a threat to withdraw or alter the offer prior to the expiration of the reasonable time period, or by providing different terms to employees who sign such an agreement prior to the expiration of the time period. You further acknowledge and agree that the release of claims in this Agreement is not provided in exchange for a raise, bonus, or as a condition of continued employment, but rather in exchange for the materially modified terms and conditions of employment during the Transition Period, eligibility for severance benefits you were not otherwise eligible to receive, and other consideration provided by the Company in this Agreement.

19.ADEA Release. You acknowledge that you are knowingly and voluntarily waiving and releasing any rights you have under the ADEA, and that the consideration given for the waiver and releases you have given in this Agreement is in addition to anything of value to which you were already entitled. You further acknowledge that you have been advised, as required by the ADEA, that: (a) your waiver and release does not apply to any rights or claims arising after the date you sign this Agreement;
(b) you should consult with an attorney prior to signing this Agreement (although you may choose voluntarily not to do so); (c) you have twenty-one (21) days to consider this Agreement (although you may choose voluntarily to sign it sooner); (d) you have seven (7) days following the date you sign this Agreement to revoke this Agreement (in a written revocation sent to the Company); and (e) this Agreement will not be effective until the date upon which the revocation period has expired, which will be the eighth day after you sign this Agreement provided that you do not revoke it (the "**Effective Date**")**.**

20.Section 1542 Waiver. In giving the release herein, which includes claims which may be unknown to you at present, you acknowledge that you have read and understand Section 1542 of the California Civil Code, which reads as follows:

> **"A general release does not extend to claims that the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the release and that, if known by him or her, would have materially affected his or her settlement with the debtor or released party."**

You hereby expressly waive and relinquish all rights and benefits under that section and any law of any other jurisdiction of similar effect with respect to your release of claims herein, including but not limited to your release of unknown claims.

21.Protected Rights. You understand that nothing in this Agreement limits your ability to file a charge or complaint with the Equal Employment Opportunity Commission, the Department of Labor, the National Labor Relations Board, the Occupational Safety and Health Administration, the Securities and Exchange Commission or any other federal, state or local governmental agency or commission ("**Government Agencies**"). You further understand this Agreement does not limit your ability to communicate with any Government Agencies or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency, including providing documents or other information, without notice to the Company. While this Agreement does not limit your right to receive an award for information provided to the Securities and Exchange Commission, you understand and agree that, to maximum extent permitted by law, you are otherwise waiving any and all rights you may have to individual relief based on any claims that you have released and any rights you have waived by signing this Agreement. Nothing in this Agreement prevents you from discussing or disclosing information about unlawful acts in the workplace, such as harassment or discrimination or any other conduct that you have reason to believe is unlawful.

22.Representations. You hereby represent that you have: been paid all compensation owed and for all hours worked; received all leave and leave benefits and protections for which you are eligible pursuant to the Family and Medical Leave Act, the California Family Rights Act, or otherwise; and not suffered any on-the-job injury for which you have not already filed a workers' compensation claim.

23.Acknowledgment. You acknowledge and agree that the negotiation of this Agreement does not constitute a termination without "Cause" or grounds for "Good Reason" under the Severance Agreement, and you also acknowledge and agree that neither the execution of this Agreement, nor any change to contractual terms by entering into this Agreement, shall constitute a termination without "Cause" or grounds for "Good Reason" under the Severance Agreement, or give rise to any benefits payable thereon.

24.Miscellaneous. This Agreement, including its exhibits, constitutes the complete, final and exclusive embodiment of the entire agreement between you and the Company with regard to its subject matter. It is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations. This Agreement may not be modified or amended except in a writing signed by both you and a duly authorized officer of the Company. This Agreement will bind the heirs, personal representatives, successors and assigns of both you and the Company, and inure to the benefit of both you and the Company, their heirs, successors and assigns. If any provision of this Agreement is determined to be invalid or unenforceable, in whole or in part, this determination will not affect any other provision of this Agreement and the provision in question will be modified by the court so as to be rendered enforceable to the fullest extent permitted by law, consistent with the intent of the parties. This Agreement will be deemed to have been entered into and will be construed and enforced in accordance with the laws of the State of Colorado without regard to conflict of laws principles. Any ambiguity in this

Agreement shall not be construed against either party as the drafter. Any waiver of a breach of this Agreement shall be in writing and shall not be deemed to be a waiver of any successive breach. This Agreement may be delivered and executed via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act or other applicable law) or other transmission method and shall be deemed to have been duly and validly delivered and executed and be valid and effective for all purposes.

If this Agreement is acceptable to you, please sign below and return the original to me. **You have twenty- one (21) calendar days to decide whether to accept this Agreement, and the Company's offer contained herein will automatically expire if you do not sign and return it within that timeframe.**

We wish you the best in your future endeavors. Sincerely,

By:_____ Dirk Thye, CEO

I HAVE READ, UNDERSTAND AND AGREE FULLY TO THE FOREGOING AGREEMENT:

Karen Smith

8/4/2023

Date

EXHIBIT A

SEPARATION DATE RELEASE
(To be signed and returned on or within 21 days after the Separation Date.)

In consideration for the severance benefits provided to me by Novosteo, Inc. ("**Novosteo**") and Quince Therapeutics, Inc. ("**Quince**," together with Novosteo, and each individually, as the context requires, the "**Company**") pursuant to the terms of the transition and separation agreement between me and the Company to which this Exhibit is attached (the "**Agreement**"), I agree to the terms below. Capitalized terms used but not defined herein shall have the meanings ascribed to them in the Agreement.

I hereby represent that: (a) I have been paid all compensation owed and have been paid for all hours worked for the Company through the Separation Date; (b) I have received all the leave and leave benefits and protections for which I am eligible pursuant to the federal Family and Medical Leave Act, California Family Rights Act or otherwise; and (c) I have not suffered any on-the-job injury for which I have not already filed a workers' compensation claim.

I hereby generally and completely release the Company and its current and former directors, officers, employees, members, participants, partners, agents, attorneys, predecessors, successors, parent and subsidiary entities, insurers, affiliates, and assigns (collectively, the "**Released Parties**") from any and all claims, liabilities and obligations, both known and unknown, that arise out of or are in any way related to events, acts, conduct, or omissions occurring prior to or on the date that I sign this Separation Date Release (the "**Release**"). This general release includes, but is not limited to: (i) all claims arising out of or in any way related to my employment with the Company, or the termination of that employment;
(ii) all claims related to my compensation or benefits from the Company, including salary, bonuses, commissions, vacation pay, paid time off, expense reimbursements, severance pay, fringe benefits, and contributions to retirement plan; (iii) all claims for breach of contract (including breach of the Severance Agreement), wrongful termination, and breach of the implied covenant of good faith and fair dealing;
(iv) all tort claims, including claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (v) all federal, state, and local statutory claims, including claims for discrimination, harassment, retaliation, attorneys' fees, or other claims arising under the federal Civil Rights Act of 1964 (as amended), the federal Americans with Disabilities Act of 1990, the federal Age Discrimination in Employment Act of 1967 (the "**ADEA**"), the Colorado Anti-discrimination Act, the Colorado Minimum Wage Order, the Colorado Labor Relations Act, the California Labor Code (as amended), and the California Fair Employment and Housing Act (as amended).

I further acknowledge and agree that, in the event I sign this Separation Date Release prior to the end of the reasonable time period, my decision to accept such shortening of time is knowing and voluntary and is not induced by the Company through fraud, misrepresentation, or a threat to withdraw or alter the offer prior to the expiration of the reasonable time period, or by providing different terms to employees who sign such an agreement prior to the expiration of the time period.

I acknowledge that I am knowingly and voluntarily waiving and releasing any rights I may have under the ADEA. I also acknowledge that the consideration given for the waiver and releases in this Separation Date Release is in addition to anything of value to which I am already entitled. I further acknowledge that I have been advised by this writing, as required by the ADEA, that: (a) my waiver and release does not apply to any rights or claims that arise after the date I sign this Separation Date Release; (b) I should consult with an attorney prior to signing this Separation Date Release; (c) I have 21 days to consider this Separation Date Release (although I may choose to voluntarily sign it sooner); (d) I have seven (7) days following the date I sign this Separation Date Release to revoke it (by providing written notice of my revocation to the Company); and (e) the Separation Date Release will not be effective until the date upon which the revocation period has expired unexercised, which will be the eighth day after I sign it (the "**Release Effective Date**").

In giving the general release herein, which includes claims which may be unknown to me at present, I acknowledge that I have read and understand Section 1542 of the California Civil Code, which reads as follows: **"A general release does not extend to claims which the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the release and that, if known by him or her, would have materially affected his or her settlement with the debtor or released party."** I hereby expressly waive and relinquish all rights and benefits under that section and any law or legal principle of similar effect in any other jurisdiction of with respect to my release of claims contained herein, including but not limited to the release of unknown and unsuspected claims.

Notwithstanding the foregoing, I am not hereby releasing any of the following claims (the "**Excluded Claims**"): (a) any rights or claims for indemnification I may have pursuant to any written indemnification agreement with the Company to which I am a party, under the charter, bylaws or operating agreements of the Company, or under applicable law; (b) any rights that cannot be waived as a matter of law; (c) any rights I have to file or pursue a claim for workers' compensation or unemployment insurance; and (d) any claims arising from the breach of this Separation Date Release. I hereby represent and warrant that, other than the Excluded Claims, I am not aware of any claims that I have or might have against any of the Released Parties that are not included in the claims released in this Release.

I agree not to disparage the Company, and the Company's officers, directors, employees, shareholders and agents, in any manner likely to be harmful to them or their business, business reputation or personal reputation. However, nothing herein shall prevent me from responding accurately and fully to any question, inquiry or request for information if required by legal process or in connection with a government investigation. In addition, nothing herein shall prevent me from: making disclosures that are protected under the whistleblower provisions of federal law or regulation or under other applicable law or regulation; engaging in any conduct permitted under the section entitled "Protected Rights" in the Agreement; filing a charge or complaint with any Government Agency; communicating with any Government Agencies; or otherwise participating in any investigation or proceeding that may be conducted by any Government Agency, including providing documents or other information, without notice to the Company. However, I understand and agree that, to the maximum extent permitted by law, I am otherwise waiving any and all rights I may have to individual relief based on any claims I have released and any rights I have waived by signing this Separation Date Release, *provided that* this Separation Date Release does not limit my right to receive any award for information provided to the Securities and Exchange Commission.

This Separation Date Release, together with the Agreement (and its exhibits), constitutes the entire agreement between me and the Company with respect to the subject matter hereof. I am not relying on any representation not contained herein or in the Agreement.

By: Karen Smith

Date: 8/4/2023

Exhibit B

CONFIDENTIAL INFORMATION AND INVENTION ASSIGNMENT AGREEMENT

(See attached)

August 1, 2023 Charles Ryan
Via Electronic Delivery

Re: Offer of Employment with Quince Therapeutics, Inc.

Dear Charles:

Quince Therapeutics, Inc. (the "Company") is pleased to offer you employment with the Company on the terms described below (the"Agreement"), beginning on September 1, 2023 or such date as otherwise agreed to by you and the Company (such actual date your employment begins (the "Start Date")).

1.Position. *AB* of the Start Date, you will initially be employed as President, Quince Therapeutics, and you will initially report to the Chief Executive Officer of the Company. As an exempt salaried employee, you may be expected to work additional hours beyond the Company's normal business hours, and you will not be eligible for overtime compensation.

2.Location. You will initially work remotely from your residence io New Jersey, while also traveling and working in Italy. The Company reserves the right to reasonably require you to perfom1 duties at places other than your primary office location from time to time, and to require reasonable business travel as needed to fulfill the duties of your role.

3.Compensation. For services to be rendered hereunder, you shall receive a base salary at the rate of $500,000 per year (the "Base Salary"), subject to standard payroll deductions and withholdings and payable in accordance with the Company's regular payroll schedule. Your Base Salary may be increased in the discretion of the Board of Directors of the Company (the "Board") from time to time. 1n addition, until the earlier of the date on which (a) your employment with the Company terminates for any reason, or (b) you elect to participate in the medical dental and/or vision plans offered by the Company for which you are eligible, the Company shall pay you an additional monthly amount of $1,800.00 to assist in covering the cost of your health insurance premiums (the "Monthly Stipend"). The Monthly Stipend will be payable in accordance with the Company's standard payroll practices and subject to all applicable withholdings a11d deductions. You may, but are not obligated to, use the Monthly Stipend to pay for health insurance premiums or other medical expenses.

4.Stock Option Grant. As a material inducement to your acceptance of this offer of employment with the Company, and subject to approval by the Board, the Company anticipates granting you an option to purchase 545,000 shares of the Company's Common Stock at an exercise price per share equal to the fair market value of the Common Stock on the date of grant (the "Option"), subject to the terms and conditions of the Company's Share Option Plan and your grant agreement.

The Option shall be subject to a vesting schedule whereby one-quarter (1/4) of the shares subject to the Option shall vest one year after grant, with the remaining shares vesting in equal monthly installments over the following three years thereafter, in each case, subject to your continuous service with the Company as of each such date.

5.Annual Cash Bonus. You will be eligible for an annual discretionary cash bonus of up to forty percent (40.0%) of your Base Salary (the "Annual Bonus"), to be prorated as of the Sta.rt Date. Whether you receive an.Annual Bonus for any given year, and the amount of any such Annual Bonus, will

be determined by the Board (or the Compensation Committee of the Board) in its sole discretion based upon the Company's and your achievement of objectives and milestones to be determined on.an annual basis. Any Annual Bonus that is awarded will be paid within the first ninety (90) days of the calendar year following the applicable bonus year. You must be employed on the day that your bonus (if any) is paid in order to earn the bonus. You will not be eligible for, and will not earn, any Annual Bonus (including a prorated bonus) if your employment terminates for any reason before the payment date.

6. Employee Benefits. You will be eligible to participate in the applicable standard benefits plans offered to similarly situated employees by the Company and its affiliates from time to time, subject to plan terms md applicable policies of the Company and its affiliates. All matters of eligibility for coverage or benefits under any benefit plan shall be determined in accordance with the provisions of such plan. The Company reserves the right to change, alter, or terminate any benefit plan or incentive compensation plan or program in its sole discretion.

7. Severance Agreement. As an additional benefit, you will be eligible for severance benefits under the terms and conditions of an Executive Change in Control and Severance Agreement presented to you by the Company (the "Severance Agreement"), attached hereto as **Attachment A** conditioned upon your and the Company's execution of the Severance Agreement.

8. Employee Confidential Information and Invention Assignment Agreement As a condition of your employment, you must sign and comply with the attached Employee Confidential Information and Invention Assignment Agreement (the "Confidentiality Agreement"), attached hereto as **Attachment B**, which prohibits unauthorized use or disclosure of the Company's proprietary information, among other obligations.

9. Company Policies. The relationship between the parties shall be subject to the Company's personnel policies and procedures as they may be adopted, re.vised or deleted from lime to time in the Company's sole discretion and yo4 agree to abide by such-policies and procedures. Notwithstanding the foregoing, in the event that the terms of this Agreement differ from or are in conflict with the Company's general employment policies or practices, this Agreement shall control.

10. Third Party Agreements and information. You represent and warrant that your employment by the Company does not conflict with any prior employment or consulting agreement or other agreement with any third party, and that you will perform your duties to the Company without violating any such agreement. You represent and warrant that you do not possess confidential information arising out of prior employment, consulting, or other third-party relationships, that would be used in connection with your employment by the Company, except as expressly authorized by that third party. During your employment by the Company, you will use in the performance of your duties only information which is generally known and used by persons with training and experience comparable to your own, common knowledge in the industry, otherwise legally in the public domain, or obtained or developed by the Company or by you in the course of your work for the Company. You also agree to honor all obligations to former employers during your employment with the Company.

11. Employment Relationship. Employment with the Company will be for no specific period of time. Your employment with the Company will be "at will," meaning that either you or the Company may terminate your employment at any time and for any reason, with or without cause or advance notice. Any contrary representations which may have been made to you are superseded by this Agreement. The "at will" nature of your employment may only be changed in an express written agreement signed by you and the Chief Executive Officer of the Company.

12. Dispute Resolution. To aid the rapid and economical resolution of disputes that may arise in connection with your employment with the Company, and in exchange for the mutual promises contained

in this Agreement, you and the Company agree that any and all disputes, claims, or causes of action, in law or equity, including but not limited to statutory claims, arising from or relating to the enforcement, breach, performance, or interpretation of this Agreement, your employment with the Company, or the termination of your employment, shall be resolved pursuant to the Federal Arbitration Act, 9 U.S.C.§ 1-16, to the fullest extent permitted by law, by final, binding and confidential arbitration conducted by JAMS, Inc. or its successor, under such arbitration service's then applicable rules and procedures appropriate to the relief being sought (available upon request and also currently available at the following web address(es): (i) https://www.jamsadr.com/rules-employment-arbitration/ and (ii) https://www.jamsadr.com/rules comprehensive-arbitration/) at a location closest to where you last worked for the Company or another mutually agreeable location. **You acknowledge that by agreeing to this arbitration procedure, both you and the Company waive the right to resolve any such dispute through a trial by jury or judge.** This provision shall not be mandatory for any claim or cause of action lo the extent applicable law prohibits subjecting such claim or cause of action to mandatory arbitration and such applicable law is not preempted by the Federal Arbitration Act or otherwise invalid (collectively, the "Excluded Claims"), including claims or causes of action alleging sexual harassment or a nonconsensual sexual act or sexual contact, or unemployment or workers' compensation claims brought before the applicable state governmental agency.

In the event you or the Company intend to bring multiple claims, including one of the Excluded Claims listed above, the Excluded Claims may be filed with a court, while any other claims will remain subject to mandatory arbitration. Nothing herein prevents you from filing and pursuing proceedings before a federal

or state governmental agency, although if you choose to pursue a claim following the exhaustion of any applicable administrative remedies, that claim would be subject to this provision. In addition, with the exception of Excluded Claims arising out of 9 U.S.C., chapter 4, all claims, disputes, or causes of action wider this section, whether by you or the Company, :must be brought in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class or representative proceeding, nor joined or consolidated with the claims of any other person or entity. The arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class proceeding. To the extent that the preceding sentences regarding class or representative claims or proceedings are found to violate applicable law or are otherwise found unenforceable, any claim(s) alleged or brought on behalf of a class or in a representative capacity shall proceed in a court of law rather than by arbitration. You will have the right to be represented by legal cou11sel at any arbitration proceeding. Questions of whether a claim is subject to arbitration under this Agreement shall be decided by the arbitrator. Likewise, procedural questions which grow out of the dispute and bear on the final disposition are also matters for the arbitrator. Notwithstanding the foregoing, provided however, that if required by applicable law, a court and not the arbitrator may determine the enforceability of this paragraph with respect to Excluded Claims. The arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award sucl1 relief as would otherwise be permitted by law; and (b) issue a written statement signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator's essential findings and conclusions ou which the award is based. The arbitrator shall be authorized to award all relief that you or the Company would be entitled to seek in a court of law. The Company shall pay all arbitration administrative fees in excess of the administrative fees that you would be required to pay if the dispute were decided in a court of law. You will also be entitled to recover your legal fees and expenses if you are the prevailing party in any proceeding against the Company. Nothing in this Agreement is intended to prevent either you or the Company from obtaining i11junctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.

13. Outside Activities During Employment.

a. Non-Company Business. Except with the prior written consent of the Board, you will not during the term of your employment with the Company undertake or engage in any other employment, occupation or business enterprise, other than ones in which you are a passive investor;

provided that the Company will not unreasonably refuse to permit you to serve on the board of directors or board of managers of one other businesses so long as they do not materially interfere with your duties hereunder. In any event, you may engage in civic and not-for-profit activities so long as such activities do not materially interfere with the performance of your duties hereunder.

b.No Adverse Interests. You agree not to acquire, assume or participate in, directly or indirectly, any position, investment or interest known to be adverse or antagonistic to the Company, its business or prospects, financial or otherwise.

14. Miscellaneous.

a.Employment Contingencies. Your employment is contingent upon a satisfactory reference check and satisfactory proof of your right to work in the United States. If the Company worms you that you are required to complete a background check, your offer of employment is contingent upon satisfactory clearance of such background check. You agree to assist as needed and to complete any documentation at the Company's request to meet these conditions.

b.Notices. Any notices provided must be in writing and will be deemed effective upon the earlier of personal delivery (including personal delivery by fax) or the next day after sending by
overnight carrier, to the Company at its primary office location and to you at the address as listed on the Company payroll

c.Severability. Whenever possible, each prov1S1on of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is .held to be invalid., illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or any other jurisdiction, but this Agreement will be reformed, construed and enforced in such jurisdiction to the extent possible in keeping with the intent of the parties.

d **Waiver.** Any waiver of any breach of any provisions of this Agreement must be in writing'to be effective, and it shall not thereby be deemed to l1ave waived any preceding or succeeding breach of the same or any other provision of this Agreement.

e.**Complete Agreement.** This Agreement, together with the Confidentiality Agreement (and Severance Agreement, if executed by the Company and you), constitutes the entire agreement between you and the Company with regard to this subject matter and is the complete, final, and exclusive embodiment of the agreement with regard to this subject matter. This Agreement is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations. It is entered into without reliance on any promise or representation other than those expressly contained herein, and it cannot be modified or amended exception a writing signed by a duly authorized officer of the Company.

f.**Counterparts.** This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, but all of which taken together will constitute one and the same Agreement.

g.**Headings.** The headings of the paragraphs hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

h.**Successors and Assigns.** This Agreement is intended tb bind and inure to the benefit of and be enforceable by you and the Company, and their respective successors, assigns, heirs, executors and administrators, except that you may not assign any of your duties hereunder and may not

assign any of your rights hereunder without the written consent of the Company, which shall not be withheld unreasonably.

i. **Tax Withholding and Indemnification.** All payments and awards contemplated or made pursuant to this Agreement will be subject to withholdings of applicable taxes in compliance with all relevant laws and regulations of all appropriate government authorities. You acknowledge and agree that the Company has neither made any assurances nor any guarantees concerning the tax treatment of any payments or awards contemplated by or made pursuant to this Agreement. You have had the opportunity to retain a tax and financial advisor and fully understands the tax and economic consequences of all payments and awards made pursuant to the Agreement.

j. **Choice of Law.** AU questions concerning the construction, validity and interpretation of this Agreement will be governed by the laws of the State of New Jersey.

If you wish to accept this offer of at-will employment, please sign and date both the enclosed duplicate original of this Agreement and the enclosed Confidentiality Agreement, and return them tome. We look forward to your joining a part of our team.

[Signature Page Follows]

Very truly yours,

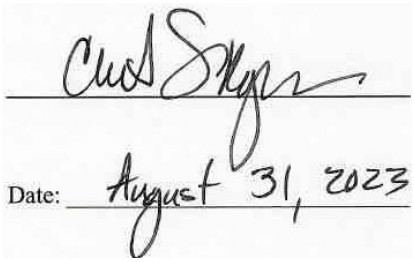
QUINCE THERAPEUTICS, INC.

By: _

Name: Dirk Thye
Title: CEO

ACCEPTED AND AGREED:

CHARLES RYAN



ATTACHMENT A SEVERANCE AGREEMENT

(See attached)

ATTACHMENT B

EMPLOYEE CONFIDENTIAL INFORMATION AND INVENTION ASSIGNMENT AGREEMENT

(See attached)

Exhibit 10.4

QUINCE THERAPEUTICS, INC.

EXECUTIVE CHANGE IN CONTROL AND SEVERANCE AGREEMENT

This Executive Change in Control and Severance Agreement (the *"Agreement')* is made and entered into by and between Charles Ryan *("Executive")* and Quince Therapeutics, Inc. (the*"Company"),* effective as of September 1, 2023 (the***"Effective Date").***

RECITALS

l. The Board of Directors of the Company (the***"Board")*** has determined that it is in the best interest of the Company and its stockholders to provide certain payments and benefits in connection with certain terminations of Executive's employment with the Company, including certain terminations that occur in connection with a Change in Control.

2. Capitalized terms used in this Agreement and not otherwise defined herein are defined in Section 6 below.

AGREEMENT

NOW, THEREFORE, in consideration of the mutual covenants contained herein, the parties hereto agree as follows:

I. At-Will Employment. The Company and Executive acknowledge that Executive's employment is and will continue to be at-will, as defined under applicable law.

2. Rights Upon Termination. Except as expressly provided in Section 3, upon the termination of Executive's employment, Executive shall only be entitled to: (i) all earned but unpaid salary, all accrued but unpaid vacation and all other earned but unpaid compensation or wages, (ii)any unreimbursed business expenses incurred by Executive on or before the termination date and which are reimbursable under the Company's business expense reimbursement policies, which will be paid to Executive promptly following Executive's submission of any required receipts and other documentation to the Company in accordance with the Company's business expense reimbursement policies, provided such receipts and documents are received by the Company within forty-five (45) days after the date of Executive's termination, and (iii) such other compensation or benefits due to Executive under any Company-provided retirement, health or equity plans, policies, and arrangements or as otherwise required by law (collectively, the ***"Accrued Benefits").***

3. Severance Benefits.

(a) Termination without Cause or Resignation for Good Reason outside of Change in Control Period. If, outside of the Change in Control Period, the Company (or any parent, subsidiary or successor of the Company) terminates Executive's employment without Cause or Executive resigns for Good Reason, then, subject to Section 4 below, Executive will receive the following severance benefits from the Company:

(i)Base Salary Severance. Executive will receive base salary severance in an amount equal to twelve (12) months of base salary at Executive's Base Salary Rate. The base salary severance shall be paid to Executive at Executive's Base Salary Rate in accordance with the Company's normal payroll practices on the Company's regularly scheduled payroll dates commencing with the first regularly scheduled payroll date that occurs at least 8 days following the Release Deadline, with the first

payment being equal to the number of business days between Executive's last day of employment and the date of the first payment multiplied by Executive's daily Base Salary Rate.

(ii) Target Annual Bonus Severance. Executive will receive a target annual bonus severance payment in an amount equal to one hundred percent (100%) of Executive's target annual bonus opportunity for the year in which the termination occurs, but pro-rated to the effective date of termination. The target annual bonus severance payment shall be paid to Executive in a single lump-sum within thirty (30) days following the termination of Executive's employment.

(iij) Benefits Severance. Executive will receive a benefits severance payment in an amount equal to twelve (12) months' of the monthly premiums that would be due for continuation coverage under Consolidated Omnibus Budget Reconciliation Act of t985, as amended ***("COBRA"),*** if Executive were to elect COBRA continuation coverage for Executive and Executive's eligible dependents (based on the coverage levels in effect immediately prior to Executive's termination or resignation and based on the premium amount that would be due for the first month of COBRA coverage if Executive were to elect such COBRA continuation coverage). The benefits severance payment shall be paid to Executive in a single lump-sum within thirty (30) days following the Release Deadline and will be made, subject to all applicable taxes and required withholdings, and regardless of whether Executive elects COBRA continuation coverage.

(iv) Equity Awards. Executive shall vest in any outstanding Equity Awards that are unvested as of Executive's termination of employment as follows: in the case of any outstanding Equity Awards that are subject to time-based vesting, 50% of any outstanding Equity Awards, and in the case of any outstanding Equity Awards that are subject to performance-based vesting, all performance goals and other vesting criteria generally will be deemed achieved at 50% of target levels as of the Executive's termination of employment. The Equity Awards will otherwise remain subject to the terms and conditions of the applicable Equity Award agreement.

(b) Termination without Cause or Resignation for Good Reason during Change in Control Period. If, during the Change in Control Period, (i) the Company (or any parent, subsidiary or successor of the Company) terminates Executive's employment without Cause or (ii) Executive resigns Executive's employment with the Company (or any parent, subsidiary or successor of the Company) for Good Reason, then, subject to Section 4 below, Executive will receive the following severance benefits from the Company:

(i) Base Salary Severance. Executive will receive a base salary severance payment in an amount equal to eighteen (18) months of base salary at Executive's Base Salary Rate. The base salary severance payment shall be paid to Executive in a single lump-sum within thirty (30) days following the Release Deadline.

(ii)Target Annual Bonus Severance. Executive will receive a target annual bonus severance payment in an amount equal to one hundred fifty percent (150%) of Executive's target annual bonus opportunity for the year in which the termination occurs, but pro-rated to the effective date of termination.The target *annual* bonus severance payment shall be paid to Executive in a single lump- sum within thirty (30) days following the Release Deadline.

(iii)Benefits Severance. Executive will receive a benefits severance payment in an amount equal to eighteen (18) months of the monthly premiums that would be due for continuation coverage under COBRA if Executive were to elect COBRA continuation coverage for Executive and Executive's eligible dependents (based on the coverage levels in effect immediately prior to Executive's termination or resignation and based on the premium amount that would be due for the first month of

COBRA coverage if Executive were to elect such COBRA continuation coverage). The benefits severance payment shall be paid to Executive in a single lump-sum within thirty (30) days following the Release Deadline and will be made, subject to all applicable truces and required withholdings, and regardless of whether Executive elects COBRA continuation coverage.

(iv) Equity Awards. Executive shall vest in any outstanding Equity Awards that are unvested as of Executive's termination of employment as follows: in the case of any outstanding Equity Awards that are subject to time-based vesting, 100% of any outstanding Equity Awards, and in the case of any outstanding Equity Awards that are subject to performance-based vesting, all performance goals and other vesting criteria generally will be deemed achieved at I00% of target levels (the "Vesting Acceleration") as of the later of Executive's termination of employment or the Change in Control. The Equity Awards will otherwise remain subject to the terms and conditions of the applicable Equity Award agreement. Notwithstanding anything stated herein or elsewhere to the contrary, if the successor to the Company or any affiliate of such successor does not agree to assume, substitute or otherwise continue any then outstanding Equity Awards at the time of a Change in Control, Executive shall receive the Vesting Acceleration as of immediately prior to and contingent upon the Change in Control unless Executive's employment with the Company (or any parent, subsidiary or successor of the Company) terminates due to Executive's resignation without Good Reason or by the Company for Cause.

(c) Resignation; Termination for Cause. If Executive's employment with the Company is terminated at any time (i) by Executive other than for Good Reason, or (ii) for Cause by the Company, then Executive will not be entitled to receive severance or other benefits pursuant to this Agreement except for the Accrued Benefits.

(d) Disability; Death. If the Company terminates Executive's employment as a result of Executive's Disability where Executive is no longer willing or able to continue performing services for the Company, or Executive's employment terminates due to Executive's death. then Executive will not be entitled to receive severance or other benefits pursuant to this Agreement except for tl1e Accrued Benefits.

(e) Breach. The parties acknowledge that Executive's entitlement to the severance payments and benefits contained in this Section 3 are of the essence and an integral part of this Agreement, and that, without such severance provisions, the parties would not enter into this Agreement. Therefore, if the Company, or any successor to the Company, breaches the tem1s of this Section 3 by failing or refusing pay or provide any of the severance payments or benefits owed to Executive in the amounts and/or according to the time periods set forth herein, Executive shall be entitled to two times (2x) the amount of severance payments and benefits that Executive would otherwise be entitled to receive pursuant to this Agreement according to the same terms set forth herein. The parties acknowledge and agree that any additional severance payments and benefits paid pursuant to this Section 3(e) constitute liquidated damages that would be incurred by Executive and that these additional severance payments and benefits are not a penalty, rather they are a reasonable amount intended as liquidated damages that will compensate Executive in the circumstances in which they are payable for the efforts and resources expended, and opportunities foregone, while negotiating and/or enforcing this Agreement and in reliance on this Agreement and on the expectation of the consummation of the transactions contemplated by this Agreement, which amounts would otherwise be impossible to calculate with precision.

4. Conditions to Receipt of Severance.

(a) Release of Claims Agreement. The receipt of any severance or other benefits pursuant to Section 3 will be subject to Executive signing and not revoking a general release of all claims in a form provided by the Company, and such release becoming effective and irrevocable no later than the sixtieth (60th) day following Executive's termination (such deadline, the ***"Release Deuclli11e").*** No

severance or other benefits will be paid or provided pursuant to this Agreement until the release becomes effective and irrevocable. If the release does not become effective and irrevocable by the Release Deadline other than as a result of an act or omission of the Company, Executive will forfeit all rights to severance payments and benefits under this Agreement.

(b) Confidential Information Agreement and Other Requirements. Executive's receipt of any payments or benefits under Section 3 will be subject to Executive continuing to comply with the terms of the Employee Confidential Information and Invention Assignment Agreement, which Executive acknowledges and agrees shall remain in full force and effect.

(c) Code Section 409A. For purposes of Section 409A of the Code, the regulations and other guidance there under and any state law of similar effect (collectively ***"Section 409A"),*** each payment that is paid pursuant to this Agreement is hereby designated as a separate payment. Further (i) no severance or benefits to be paid or provided to Executive, if any, pursuant to this Agreement that, when considered together with any other severance payments or benefits, are considered deferred compensation under Section 409A, will be paid or otherwise provided until Executive has had a "separation from service" within the meaning of Section 409A, (ii) no severance or benefits to be paid or provided to Executive, if any, pursuant to this Agreement that are intended to be exempt from Section 409A pursuant to Treasury Regulation Section 1.409A-1{b)(9)(iii) will be paid or otherwise provided until Executive has bad an "involuntary separation from service" within the meaning of Section 409A, and (iii) in the case of (i) and (ii), any reference in this Agreement to "termination•·or "termination of employment" or any similar term shall be construed to mean a "separation from service" within the meaning of Section 409A. The parties intend that all payments and benefits provided or to be provided under this Agreement comply with, or are exempt from, the requirements of Section 409A so that none of the payments or benefits will be subject to the adverse tax penalties imposed under Section 409A, and any ambiguities herein will be interpreted to so comply or be so exempt. The Company and Executive agree to work together in good faith to consider amendments to this Agreement, and to take such reasonable actions, which are necessary, appropriate or desirable to avoid imposition of any additional tax or income recognition under Section 409A before payments or benefits are provided to Executive. Any severance payments or benefits made in connection with Executive's termination under this Agreement and provided on or before the 15th day of the 3rdmonth following the end of Executive's first tax year in which Executive's termination occurs or, if later, the 15th day of the 3rd month following the end of the Company's first tax year in which Executive's termination occurs, shall be exempt from Section 409A to the maximum extent permitted pursuant to Treasury Regulation Section 1.409A-1(b)(4) and any additional payments or benefits provided in connection with Executive's termi11ation under this Agreement shall be exempt from Section 409A to the maximum extent permitted pursuant to Treasury Regulation Section 1.409A-1(b)(9)(iii) (to the extent it is exempt pursuant to such section it will in any event be provided no later than the last day of Executive's 2nd taxable year following the taxable year in which Executive's termination occurs). Notwithstanding the foregoing, if any of the payments or benefits provided in connection with Executive's termination do not qualify for any reason to be exempt from Section 409A pursuant to Treasury Regulation Section 1.409A-1(b)(4), Treasury Regulation Section 1.409A-1{b)(9)(iii), or any other applicable exemption and Executive is, **at** the time of Executive's termination, a "specified employee," as defined in Treasury Regulation Section 1.409A-I (i), each such payment or benefit will not be provided until the first regularly scheduled payroll date that occurs on or after the date six (6) months and one (1) day following Executive's termination and, on such date (or, if earlier, another date that occurs as soon as practicable after Executive's death), Executive will receive all payments and benefits that would have been provided during such period in a single lump sum, if applicable. In addition, notwithstanding any other provision herein to the contrary, to the extent that any reimbursements or in-kind benefits under this Agreement or otherwise constitute non- exempt "nonqualified deferred compensation" within the meaning of Section 409A, then any such reimbursements and/or benefits (i) shall be made or provided promptly but no later than December 31st of the calendar year following the year in which the expense was incurred by Executive, (ii) shall not in any way affect the

expenses eligible for reimbursement or in-kind benefits to be provided in any other calendar year, and (iii) shall not be subject to liquidation or exchange for another benefit.

5.Limitation on Payments. In the event that the severance benefits provided for in this Agreement and/or other payments and benefits otbe1Wise provided to Executive (i) constitute "parachute payments" within the meaning of Section 280G of the Code and (ii) but for this Section 5, would be subject to the excise tax imposed by Section 4999 of the Code, then, at the election of Executive, Executive's severance benefits under Section 3, and/or the other payments and benefits otherwise provided to Executive, will be either:

(a) delivered in full, or

(b) delivered as to such lesser extent which would result in no portion of such severance benefits being subject to excise tax under Section 4999 of the Code,

whichever of the foregoing amounts, taking into account the applicable federal, state and Local income taxes and the excise tax imposed by Section 4999, results in the receipt by Executive on an after-tax basis, of the greatest amount of severance benefits and other payments and benefits, notwithstanding that all or some portion of such severance benefits and other payments and benefits may be taxable under Section 4999 of the Code. Unless the Company and Executive otherwise agree in writing, any determination required under this Section *5* will be made in writing by the Company's outside legal counsel or independent public accountants or other firm selected by the Company (the ***"Firm"),*** whose determination will be conclusive and binding upon Executive and the Company for all purposes. For purposes of making the calculations required by this Section 5, the Firm may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code.The Company and Executive *will* furnish to the Firm such information and documents as the Firm may reasonably request in order to make a determination under this Section. The Company will bear all costs the Firm may reasonably incur in connection with any calculations contemplated by this Section 5. Any reduction made pursuant to this Section *5* shall be made in accordance with the following order of priority: (i) stock options whose exercise price exceeds the fair market value of the optioned stock ***("Underwater Options")*** (ii) Full Credit Payments (as defined below) that are payable in cash, (iii) non-cash Full Credit Payments that are taxable, (iv) non-cash Full Credit Payments that are not taxable (v) Partial Credit Payments (as defined below) and (vi) non-cash employee welfare benefits. In each case, reductions shall be made in reverse chronological order such that the payment or benefit owed on the latest date following the occurrence of the event triggering the excise tax will be the first payment or benefit to be reduced (with reductions made pro-rata in the event payments or benefits are owed at the same time).

6.Definition of Terms. The following terms referred to in this Agreement will have the following meanings:

(a) Base Salary Rate. For purposes of this Agreement, *"**Base Salary Rate**"* means Executive's base salary rate as in effect immediately prior to the date of Executive's termination of employment (provided, if Executive resigns as a result of Section 6(i)(ii}, "Base Salary Rate" shall mean Executive's base salary rate as in effect immediately prior to the reduction triggering Section 6(i)(ii)).

(b) Cause. For purposes of this Agreement, *"**Cause**"* shall mean the Executive's: (i) breach of a fiduciary duty owed by the Executive to the Company or its respective shareholders; (ii) willful misconduct or gross negligence in the performance of the Executive's material duties; (iii) the Executive's failure to comply with the written, lawful instruction of the Board which are consistent with Executive's duties as Chief Business Officer of the Company; (iv) fraud, embezzlement or other dishonesty with respect to the Company or its affiliates (but with respect to dishonesty, excluding the de minimis use of Company

resources or services for personal reasons); (v) conviction, plea of nolo contendere, guilty plea, or confession to any felony or any crime based upon an act of fraud, embezzlement or moral turpitude (excepting any non-felony traffic offenses); (vi) the Executive being under the influence of alcohol during working hours or under the influence of controlled substances at any time unless taken pursuant to a valid prescription provided by a medical professional (excepting alcohol consumed at a Company party or similar social event), or (vii) a material breach of this Agreement, provided that with respect to conduct subject to (ii), (iii), (vi) or (vii), if curable, shall not constitute Cause unless the Board has (A) determined by the affirmative vote of a majority of the entire Board that Cause exists and (B) provided the Executive with written notice of the acts or omissions giving rise to a termination of his employment for Cause and the Executive fails to correct the act or omission within thirty (30) days after receiving the Company's notice (the ***"Cure Period").***

(c) Code. For purposes of this Agreement, ***"Code"*** means the Internal Revenue Code of 1986, as amended.

(d) Change in Control. For purposes of this Agreement, ***"Change in Control"*** shall have the meaning set forth in the Plan.

(e) Change in Control Period. For purposes of this Agreement, ***"Change in Control Period"*** means the period beginning three (3) months prior to, and ending eighteen (18) months following, a Change in Control.

(f) Disability. For purposes of this Agreement, ***"Disability"*** means total and permanent disability as defined in Section 22(e)(3) of the Code.

(g) Equity Award. For purposes of this Agreement,***"Equity Award"*** means each then outstanding award relating to the Company's common stock (whether stock options, stock appreciation rights, shares of restricted stock, restricted stock units, performance shares, performance units or other similar awards).

(h) Full Credit Payment. For purposes of this Agreement, ***"Full Credit Payment"*** means a payment, distribution or benefit., whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise, that if reduced in value by one dollar reduces the amount of the parachute payment (as defined in Section 2800 of the Code) by one dollar, determined as if such payment, distribution or benefit had been paid or distributed on the date of the event triggering the excise tax.

(i) Good Reason. For purposes of this Agreement, resignation for ***"Good Reason"*** means Executive's resignation due to the occurrence of any of the following conditions which occurs without Executive's written consent, provided that the requirements regarding advance notice and an opportunity to cure set forth below are satisfied:

(i)One or more adverse changes to Executive's authority, duties or responsibilities that, individually or taken as a whole, results in a material diminution in Executive's authority, duties or responsibilities in effect prior to such change or changes;

(ii)A 10% or more reduction in Executive's base salary from its highest level or a 10% or more reduction in Executive's base compensation (including base salary and target bonus) from its highest level;

(iii)The Company conditions Executive's continued service with the Company on the relocation of Executive's principal work location to a location that is more than twenty (20) miles from Executive's then current principal work location and such relocation results in an increase in Executive's one-way commuting distance from Executive's home by twenty (20) miles or more;

(iv)The failure of the Company to obtain the assumption of this Agreement by any successor to the Company; or

(v) Any material breach or material violation of a material provision of this Agreement by the Company (or any successor to the Company).

ln order for Executive to resign for Good Reason, Executive must provide written notice to the Company of the existence of the Good Reason condition within ninety (90) days of bis discovery of existence of such Good Reason condition. Upon receipt of such notice, the Company will have thirty (30) days during which it may remedy the Good Reason condition and not be required to provide the severance payments and benefits described herein as a result of such proposed resignation; provided that the Company's cure right shall be no more than ten (I0) days for the failure to pay any compensation to Executive when due. If the Good Reason condition is not remedied within the applicable cure period, Executive may resign based on the Good Reason condition specified in the notice effective no later than ninety (90) days following the expiration of the applicable cure period.

(j) Partial Credit Payment. For purposes of this Agreement, ***"Partial Credit Payment"*** means any payment, distribution or benefit that *is* not a Full Credit Payment. bl no event shall Executive have any discretion with respect to the ordering of payment reductions.

(k) Plan. For purposes of this Agreement, ***"Plan"*** means the Company's 2019 Equity Incentive Plan.

7. Successors.

(a) Company Successors. Any successor to the Company (whether direct or indirect and whether by purchase, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets shall assume the obligations under this Agreement and agree expressly to perform the obligations under this Agreement in the same manner and to the same extent as the Company would be required to perform such obligations in the absence of a succession. For all purposes under this Agreement, the term "Company" will include any such successor to the Company's business and/or assets.

(b) Executive's Successors. The terms of this Agreement and all rights of Executive hereunder will inure to the benefit of, and be enforceable by, Executive's personal or legal representatives, executors, administrators, successors, heirs, distributes, devisees and legatees.

8. Notice.

(a) General. Notices and all other communications contemplated by this Agreement will be in writing and will be deemed to have been duly given when personally delivered or when mailed by U.S. registered or certified mail, return receipt requested and postage prepaid. In the case of Executive, mailed notices *will* be addressed to Executive at the home address which Executive most recently communicated to the Company in writing. In the case of the Company, mailed notices will be addressed to its corporate headquarters, and all notices will be directed to the attention of the Company's Secretary (or, if Executive is the Company's Secretary, any other executive officer of the Company).

(b) Notice of Termination. Any termination by the Company for Cause or by Executive for Good Reason or as a result of a voluntary resignation will be communicated by a notice of termination to the other party hereto given in accordance with Section 8(a) of this Agreement. Such notice will indicate the specific termination provision in this Agreement relied upon, will set forth in reasonable detail the facts and circumstances claimed to provide a basis for termination under the provision so indicated, and will specify the termination date.

9. Miscellaneous Provisions.

(a) No Duty to Mitigate. Executive will not be required to mitigate the amount of any payment contemplated by this Agreement, nor will any earnings that Executive may receive from any other source reduce any such payment.

(b) Waiver. No provision of this Agreement will be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by Executive and by an authorized officer of the Company (other than Executive). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party will be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(c) Headings. All captions and section headings used in this Agreement are for convenient reference only and do not forma part of this Agreement.

(d) Choice of Law. The validity, interpretation, construction and performance of this Agreement will be governed by the laws of the State of California (with the exception of its conflict of law provisions).

(e) Legal Fees. In the event of litigation with respect to this Agreement the substantially prevailing party shall be entitled to recover his or its legal fees and expenses.

(f) Entire Agreement. This Agreement represents the entire agreement and understanding between the parties hereto and supersedes all prior or contemporaneous agreements with respect to the subject matter of this Agreement. Further, this Agreement supersedes in their entirety any and aJI prior offer letters or employment agreements entered into by and between Executive and the Company, which offer letters and employment agreements shall be null and void. No waiver, alteration, or modification of any of the provisions of this Agreement will be binding unless in writing and signed by duly authorized representatives of the parties hereto and which specifically mention this Agreement. In entering into this Agreement, no party has relied on or made any representation, warranty, inducement, promise, or understanding that is not in this Agreement. To the extent that any provisions of this Agreement conflict with those of any other agreement between Executive and the Company, the terms in this Agreement will prevail.

(g) Severability. In the event that any provision or any portion of any provision hereof becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable, or void, this Agreement will continue in full force and effect without said provision or portion of provision. The remainder of this Agreement shall be interpreted so as best to give effect to the intent of the Company and Executive.

(h) Taxes, Withholding and Required Deductions. All payments and, if applicable, benefits made pursuant to this Agreement will be subject to all applicable taxes, withholding of taxes, and any other required deductions.

(i) Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be deemed an original, and all of which together shall constitute one and the same agreement. Execution of a facsimile or scanned copy will have the same force and effect as execution of an original, and a facsimile or scanned signature will be deemed an original and valid signature.

(Remainder of page intentionally left blank)

IN WITNESS WHEREOF, each of the parties has executed this Agreement, in the case of the Company by its duly authorized officer, as of the date first set forth above.

THE COMPANY:

QUINCE TIIERAPEUTICS, lNC.

By: ____

Name: Dirk Thye
Title: CEO

EXECUTIVE

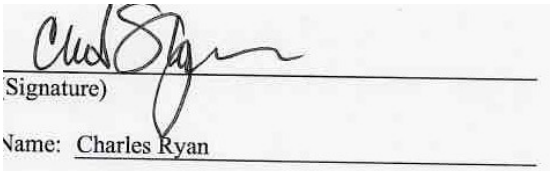


Exhibit 31.1

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Dirk Thye, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Quince Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2023

/s/ Dirk Thye

Dirk Thye
President, Chief Executive Officer and Chairman of our Board of Directors
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Brendan Hannah, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Quince Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2023

/s/ Brendan Hannah

Brendan Hannah

Chief Business Officer and Chief Operating Officer

(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002 (18 U.S.C. SECTION 1350)

In connection with the Quarterly Report of Quince Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 14, 2023

By: /s/ Dirk Thye

Dirk Thye
President and Chief Executive Officer
(Principal Executive Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Quince Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

CERTIFICATION PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002 (18 U.S.C. SECTION 1350)

In connection with the Quarterly Report of Quince Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 14, 2023

By: /s/ Brendan Hannah

Brendan Hannah
Chief Business Officer and Chief Operating Officer
(Principal Financial Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Quince Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.